The Influence of Pulmonary Staple Line Reinforcement on Air Leaks*

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Objectives: Although uncommon, prolonged postoperative air leaks are a troublesome complication of lung surgery. This study was performed to determine if buttressing pulmonary staple lines would reduce air leakage at varying airway pressures, and if there was a difference between buttressing materials.

Methods: Using cadaver lungs, the development of air leak from staple lines was evaluated at incremental airway pressures. Unreinforced staples were compared to staples reinforced with bovine pericardium and staples reinforced with expanded polytetrafluorethylene (ePTFE).

Results: Unreinforced staple lines began to leak air at an airway pressure of 20 mm Hg, and > 90% leaked at a pressure of 35 mm Hg. Both bovine pericardium and ePTFE significantly reduced the incidence of air leak at these airway pressures. At higher airway pressures, ePTFE was superior to bovine pericardium.

Conclusion: Staple line reinforcement with either material protects against air leak. Patients at risk for elevated airway pressures and/or postoperative ventilator support should be considered for utilization of these staple reinforcing materials. (CHEST 2002; 122:2146–2149)

Key words: air leak; reinforcement; stapling

Abbreviations: ePTFE = expanded polytetrafluorethylene; GIA = GI anastomosis; LVRS = lung volume reduction surgery

Pulmonary surgery often requires the division of lung parenchyma. The free edge of the divided lung tissue is a potential source for the leakage of both air and blood. The pulmonary margin can be secured with either sutures or staples in an effort to prevent these undesirable events. Surgical stapling devices offer a secure system of tissue approximation and are widely utilized for nonanatomic lung resections, division of the pulmonary fissure during a lobectomy, and during the extensive excision of lung tissue required for lung volume reduction surgery (LVRS). The stapler provides reliable hemostasis, but it does not consistently obtain an airtight closure. Although troublesome postoperative air leaks are infrequent, they can significantly prolong a patient’s hospitalization. Air leaks from pulmonary staple lines can be caused by several factors: tissue fragility, excessive tissue tension, and surgical techniques. LVRS is unique because of the length of the staple lines and the poor quality of the lung parenchyma. These factors combine to make a prolonged air leak one of the most common sources of morbidity for LVRS.

Reinforcement of staples with various materials is a strategy employed to diminish and perhaps eliminate pulmonary air leakage. The ideal reinforcing material should possess several properties: (1) ease of use, (2) biocompatibility, (3) the combination of flexibility and strength, (4) airtightness, and (5) cost-effectiveness. The two most commonly used staple reinforcement materials are bovine pericardium and expanded polytetrafluorethylene (ePTFE). Our study compared the effectiveness, over a range of airway pressures, of simple staples vs staple line reinforcement with either bovine pericardium or ePTFE in the prevention of air leaks.

Materials and Methods

This study used fresh, frozen, human cadaver thoraces. The cadavers were all adults without gross evidence of significant pulmonary disease. The cadavers were thawed to room temperature, which resulted in a tissue turgor similar to a fresh cadaver. The trachea was transected proximal to the carina and intubated.
with a cuffed endotracheal tube. A manometer was placed into the circuit, and positive pressure was generated and sustained by hand ventilation.

The 10 cadavers had their lungs exposed via a sternotomy incision. There were a total of 75 firings of GIA anastomosis (GIA) staplers. There were 25 staple lines in each of three groups: group 1, simple, unreinforced staples; group 2, bovine pericardium-reinforced staples; and group 3, ePTFE-reinforced staples. The staple lines for each group were equally dispersed between lobes of the lung, orientation of staple placement, and with each lung receiving a minimum of one stapling from each group. Each staple line was widely spaced in order to isolate each site and prevent both staple overlap and the inclusion of excessive tissue in the staple line. No single lung had more than four staple lines. The staplers were carefully applied, activated, and released in order to prevent inadvertent tearing of the lung parenchyma. Two different GIA stapling devices from the same manufacturer were used to evaluate the stapler as a potential cause of an air leak. Each group had 12 firings using the EZ45 stapler (Ethicon; Somerville, NJ) and 13 firings using the Proximate 75 stapler (Ethicon).

Starting at 15 cm H2O, the airway pressure was increased in increments of 5 cm H2O until either an air leak was discovered or the airway pressure reached 60 cm H2O. An air leak was identified by the escape of air through the staple line. Water was dripped over each staple line in order to aid in the identification of escaping air. Each assessment was made by at least two of the authors.

The presence or absence of an air leak was noted for each staple line at each ascending level of airway pressure. A staple line with no air leak was considered a survivor. We used the SAS LIFETEST procedure (SAS Institute; Cary, NC) to compute nonparametric estimates of the survival distribution function. Both the Wilcoxon test and the generalized Savage or log-rank test were used to test the equality of the survival functions. Significance was attributed to p values < 0.05.

### Results

The two GIA stapling devices did not independently influence the development of air leaks. The lack of difference between the staplers allowed the combining of all results for statistical analysis.

There was a direct relationship between airway pressure and the development of leaks for both unreinforced and reinforced staple lines. At an airway pressure of 15 cm H2O, there was no escape of air from any of the staple line groups. This finding confirmed the absence of any accidental lung trauma as a cause of an air leak. However, over the range of 20 to 55 cm H2O, there were an ascending number of air leaks as the airway pressure increased; this relationship was observed for all three groups. The results are shown in Table 1 as the percentage of staple lines surviving without an air leak at each pressure level.

The estimated 95% confidence interval for the median survival pressure is 20 to 25 cm H2O for the unreinforced staples, 40 to 55 cm H2O for the bovine pericardium group, and at least 55 cm H2O for the ePTFE group.

### Table 1—Leaking Staple Lines*

<table>
<thead>
<tr>
<th>Airway Pressure, mm Hg</th>
<th>No Reinforcement</th>
<th>Bovine Pericardium</th>
<th>ePTFE</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>20</td>
<td>10 (40)</td>
<td>0 (0)</td>
<td>0 (0)</td>
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<tr>
<td>25</td>
<td>19 (76)</td>
<td>1 (4)</td>
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</tr>
<tr>
<td>30</td>
<td>21 (84)</td>
<td>2 (8)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>35</td>
<td>23 (92)</td>
<td>4 (16)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>40</td>
<td>23 (92)</td>
<td>8 (32)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>45</td>
<td>24 (96)</td>
<td>9 (36)</td>
<td>3 (12)</td>
</tr>
<tr>
<td>50</td>
<td>24 (96)</td>
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<td>3 (12)</td>
</tr>
<tr>
<td>55</td>
<td>25 (100)</td>
<td>21 (84)</td>
<td>11 (44)</td>
</tr>
</tbody>
</table>

*Data are presented as No. (%).

The Kaplan-Meier survival curves are shown in Figure 1. Both the Wilcoxon and log-rank tests give a p value < 0.0001 for the three-group comparison, demonstrating differences in survival in the three groups. Also, results of the two-group comparisons are all statistically significant: unreinforced vs bovine pericardium (p < 0.0001), unreinforced vs ePTFE (p < 0.0001), and ePTFE vs bovine pericardium (p = 0.001).

### Discussion

During the performance of routine pulmonary surgery, a GIA stapling device is often used for the division of lung tissue. Although air leaks are generally small volume and of a short duration, there are troublesome exceptions. The introduction of LVRS has provided an operation where pulmonary air leaks are a more common problem. A persistent air leak in LVRS remains a significant complication that prolongs both the length of hospitalization and duration of pleural drainage.1

Several different materials have been advocated for staple reinforcement without evidence of a clear advantage for any one technique.2–6 Bovine pericardium and ePTFE have emerged as the two most widely used materials for pulmonary staple line reinforcement.

The causes of stapler related air leaks are multifactorial. There is a direct relationship between the length of the staple line and possibility of developing an air leak. Thin and friable parenchyma is susceptible to mechanical stress resulting in tissue tearing. An additional mechanical stress can be caused by movement of the stapler. Excessive tissue tension during staple application can result in a significant air leak. This elevated tissue tension is caused by either the inclusion of excessive tissue between the staple jaws or the overlapping of staple lines. Many pulmonary air leaks can be avoided by using careful surgical

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technique; however, others are inherent in the lengths of the staple lines, the fragility of the lung tissue, or the anatomic constraints of the pulmonary operation.

Our results indicate that simple unreinforced staples do not leak at airway pressures < 20 cm H₂O. However, at 20 cm H₂O, nearly 50% leak air; at 25 cm H₂O, 76% allow air to escape. These values are important since staple lines are exposed to these pressures during uncomplicated positive pressure ventilation. This rate of staple line air leakage at pressures ≤ 25 cm H₂O can be decreased to essentially zero using either bovine pericardium or ePTFE as a staple reinforcement. Another in vitro study has confirmed that buttressing of staples, when compared to unreinforced staples, increases the airway pressure needed to produce leaks.¹ In this study, ePTFE-reinforced staple lines leaked at an airway pressure 11.8 cm H₂O greater than simple unreinforced staples. Unfortunately, this study did not report the actual airway pressures, which prevents a direct comparison to our results. Clinically, there have been reported observations that reinforcement of staples in LVRS decreases air leakage.² ³ ⁴ The clinical evidence favoring staple line reinforcement includes a combination of clinical observations: intraoperative staple line examination, the decreased volume of air leakage via chest tubes, and the reduced duration of chest tube drainage of air.

Our results indicate that at airway pressures up to 25 cm H₂O, both bovine pericardium and ePTFE reinforcement exert the same degree of protection from the development of staple line air leaks. As the airway pressures were > 25 cm H₂O, the reinforced staple lines also lose their integrity. The ePTFE demonstrated a statistically significant advantage when compared to the bovine pericardium at each tested airway pressure ≥ 25 cm H₂O. When the airway pressure reached 50 cm H₂O, 48% of bovine pericardium-reinforced staples leaked air compared to 12% of the ePTFE-reinforcement group. These findings are potentially significant when this range of elevated airway pressures are achieved in clinical practice.

Minimizing the duration of positive pressure ventilation is critical to the prevention of air leakage from the stapled lung. This can be achieved by a policy of early extubation after all operations, especially LVRS. If ventilator support is required, careful attention to ventilator management is required in an effort to minimize airway pressure.

Bovine pericardium and ePTFE share similar characteristics. Both materials are nonbiologic and inert. Bovine pericardium strips are glutaraldehyde

![Survival Rate Comparison](image)

**Figure 1.** Survival from air leaks of unreinforced staple lines and staples reinforced with either ePTFE or bovine pericardium (BP) is depicted. Survival or freedom from air leaks was significantly different for all comparisons.
fixed and either preserved in a solution that contains propylene oxide or require rehydration with a wetting gel. Neither bovine pericardium nor ePTFE have been reported to increase the risk of infection when used as a staple line buttress material despite being foreign materials. Bovine pericardium has been hypothesized to possess antibacterial properties secondary to the leaching of retained glutaraldehyde molecules. The small pore size of the ePTFE, combined with its encapsulation by fibrous tissue appears to protect it from bacterial invasion.

The use of these buttressing materials adds increased effort and time to the stapling process. Overall, however, the ePTFE and bovine pericardium materials are both easy to handle and simple to apply. The cost is similar for both materials. It was anticipated that the added cost of staple reinforcement would be offset by their effectiveness in decreasing air leaks, which would subsequently decrease the duration of hospitalization. However, one study found that the economic advantage for staple line reinforcement with bovine pericardium reinforcement was absent because the added cost of the bovine pericardium was nearly identical to the decreased charges for the shorter hospital stay. Interestingly, this study only evaluated unilateral LVRS; this would imply that bilateral lung stapling using bovine pericardium would significantly increase costs. The lack of savings, however, does not negate the clinical benefit of decreased duration of chest tube drainage and length of hospitalization.

The biological response to ePTFE and bovine pericardium can be extrapolated from animal studies. A study performed in dogs evaluated the biological response after 5 months to pulmonary staple line reinforcement using ePTFE and bovine pericardium. The bovine pericardium was found to be grossly intact although deformed, but with no degradation of the collagen fibrils or calcification. The lateral borders of the bovine pericardium had retracted away from the lung without the formulation of cellular or fibrous continuity. The fibrous capsule for the bovine pericardium was statistically thinner than that seen with the ePTFE. In addition to extensive encapsulation, the ePTFE demonstrated a relatively acellular fibrocollagenous interface with the lung parenchyma. There was microscopic evidence of collagen deposition into the ePTFE, providing a continuous material-tissue interface. These findings indicate a physical incorporation of the ePTFE with the lung when compared to the bovine pericardium. The ePTFE had extensive fibrous pleural adhesions, whereas the bovine pericardium had infrequent development of attachment to the chest wall. Since some LVRS patients require reoperation, such as later lung transplantation, the paucity of parietal pleural attachments could favor the use of bovine pericardium in these individuals.

A theoretical problem involves the use of bovine pericardium and the risk for transmissible spongiform encephalopathy. The World Health Organization has recommended that whenever possible cattle sources should be avoided for medical products. However, there has been no evidence of transmission of this fatal disease by medical materials derived from a bovine source.

Alternative and/or complementary techniques to staple line reinforcement to reduce air leaks from the lung parenchyma have been reported, including the use of a collagen-reinforced polyglycolic mesh and a liquid sealant. Neither techniques appears to be either superior or complementary to either the bovine pericardium or ePTFE.

The issue of pulmonary staple line air leaks is important to thoracic surgeons. Definitive recommendations regarding the indications and selection of the best buttressing material await the result of more clinical experience. Our conclusion from this experimental assessment is that pulmonary staple lines should be routinely reinforced with one of these materials in all patients considered at risk for postoperative air leaks. There may be an advantage in using ePTFE for patients exposed to excessive (> 35 cm H₂O) airway pressures.

References