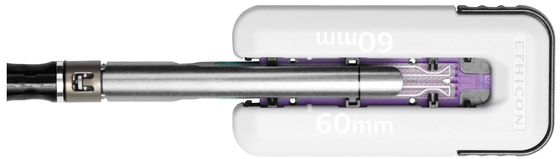
Use of a novel Staple Line Reinforcement significantly reduces air leaks in a porcine stapled lung wedge resection model

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Objective

Many strategies are employed by surgeons to reduce the risk of leak and bleeding during transection of tissue across specialties. Specifically, prolonged air leak is a common complication of thoracic surgery, occurring after 24-26% of lung resection surgeries[1]. A novel Staple Line Reinforcement (SLR) buttress material of polyglactin 910 and polydioxanone has demonstrated improved reinforcement, absorption, and loading without sacrificing hemostasis or usability[2]. The purpose of this study is to investigate its potential to reduce air leaks in stapled lung resections using an ex vivo model.



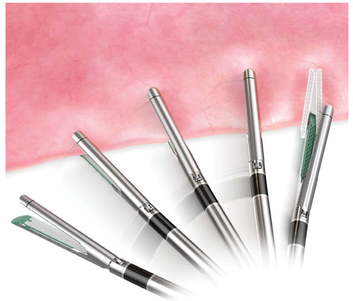


Figure 1. (above) Application of novel SLR to surgical stapling device

Figure 2. (left) Representation of use of stapler with SLR

Methods

Stapled wedge resection was performed on a total of 50 porcine lungs using standard endocutters (ECHELON™+ 60mm Stapler, PCEE60A, PSEE60A, and PLEE60A), 25 in a control group using a standard cartridge (Blue GST 60mm reloads, GST60B) and 25 in an experimental group using a standard cartridge with SLR (ECHELON ENDOPATH™ Staple Line Reinforcement, ECH60R). Using a previously described ex vivo physiologic porcine lung model[3] (Fig. 3), the specimens were then evaluated for presence, rate, and volume of air leak over 10 minutes of positive pressure ventilation (PPV).

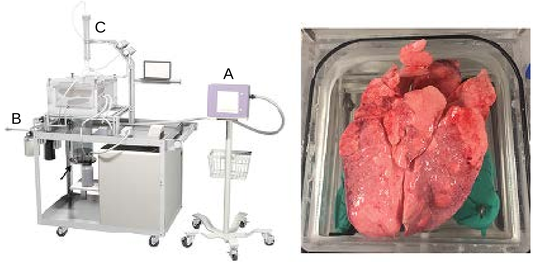


Figure 3.
Figure 3.1. Schematic of the ex vivo lung chamber consisting of clinical ventilator-controlled PPV (A), compressor and PEEP valve maintained a set compliance in the chamber (B), and leak quantification system including air collection cylinder, air removal pump, recirculation pump, and ultrasonic level sensor (C)
Figure 3.2. Lungs in the chamber with trachea cannulated (behind upper lobes)

Results

Under PPV, zero (0/25) leaks were observed in the SLR group vs 11/25 (44%) in the control group ($p<0.001$, Figure 4). The median leak volume was 0 mL in both groups, while the control group had a 3rd quartile leak volume of 69.6 mL and a maximum of 965.8 mL ($p<0.001$, Figure 5). When an air leak did occur in the control group, 7/11 (64%) were located at the thin lung edges.

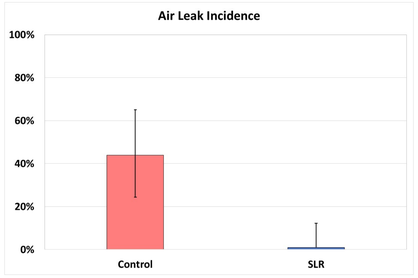


Figure 4. Incidence of air leak by experimental group with 95% Confidence Interval

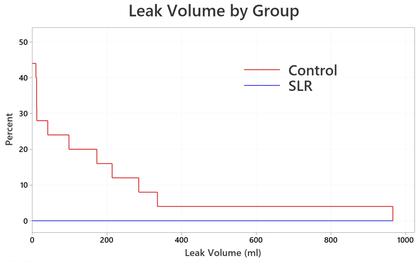


Figure 5. Failure mode-type graph showing percentage of group by air leak volume

Conclusions

Use of the SLR significantly reduced air leak occurrence in a physiologic lung model under PPV. Furthermore, the majority of observed air leaks that occurred in the control group were at the thin edges of the lung. These findings demonstrate potential for SLR addressing the complex clinical problem of prolonged air leak. We hypothesize that the addition of the SLR may help provide support to the staple line at these thin edges, and that these results may additionally translate to application on other organ resections including hollow viscera. Future studies are ongoing to examine performance of the SLR in other organ systems in both preclinical models and clinical trials.

References

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