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CLINICAL RESEARCH

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Ex vivo comparative evaluation of feline hilar lung lobectomy using linear stapler, pretied ligature loop, and double-shank titanium clips

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Abstract

Objective: To compare the seal performance of a linear vascular stapler, pretied ligature loop (PLL), and double-shank (DS) titanium clip for total lung lobectomy in a feline cadaveric model under physiologic and supraphysiologic airway pressures.

Study design: Ex vivo experimental randomized study.

Sample population: Thirty cadaveric feline lung lobes.

Methods: Thirty lung lobes from five fresh feline cadavers, humanely euthanized for reasons unrelated to this study, were randomized into three groups to undergo hilar lung lobectomy using a linear vascular stapler, PLL, or DS titanium clips. After lobectomy, each bronchial stump was submerged in water, and the peak inspiratory airway pressure was increased up to 40 cm H_2O. Bursting pressure was compared across the techniques.

Results: No air leaks were observed in the PLL or DS titanium clip groups. One bronchial stump (1/10) in the linear vascular stapler group leaked at the supraphysiologic pressure of 40 cm H_2O. There was no difference in leakage incidence among the groups ($p = .33$).

Conclusion: Linear vascular stapler, PLL, or DS titanium clips were comparable and effective devices for sealing the hilar lung lobectomy site at physiologic and supraphysiologic airway pressure in feline cadavers. The PLL and DS titanium clips were relatively easy to use, required less working space, and may represent an equally effective and more cost-efficient alternative to traditional stapling devices in open and minimally invasive feline pulmonary lobectomy.

1 | INTRODUCTION

Lung lobectomy in small animals is indicated for pulmonary neoplasia,[1,2] pulmonary pneumonia and abscesses,[3] chronic pyothorax,[4] lung lobe trauma,[5] lung torsion,[6] pulmonary bullae, cysts, and blebs,[7,8] foreign bodies not

Abbreviations: CT, computed tomography; DS, double shank; ET, endotracheal; PLL, pretied ligature loop; TA, thoracoabdominal; VATS, video-assisted thoracoscopy.

removable via bronchoscopy,[9] and bronchoesophageal fistula.[10] Lung lobectomy is usually performed via a lateral thoracotomy or median sternotomy.[1] However, in the last decade, lung lobectomy using minimally invasive techniques such as thoracoscopy,[11,12] and video-assisted thoracoscopy (VATS)[13–16] developed considerably with the intent of reducing morbidity and improving postoperative recovery.[17] Closure of the hilar blood vessels and bronchi for complete lung lobectomy can be achieved by ligation,[18] surgical staples,[14,16,18] self-locking devices,[16,19] surgical clips,[20,21] or pretied ligature loops (PLL).[22]

The use of linear stapling is the standard of care and is considered faster than individual ligation of bronchi and blood vessels but the use of traditional stapling devices may be challenging in small patients due to the limited space in the thoracic cavity. Moreover, the difficulty in gaining access to the pulmonary hilus may prevent complete excision of the affected tissue, increasing the surgical time and risk of iatrogenic damage to surrounding anatomic structures.[1,16,23] Limited access to the thoracic cavity may also impair adequate staple application, and disruption of a staple line can result in pneumothorax and hemothorax.[1,24]

Pretied ligature loops, which consist of a slipknot and knot-pushing tube device, provide a feasible and safe alternative for ligation in canine lung biopsy up to 3 cm from the lung lobe margin,[17] and for total lung lobectomy in both open and minimal invasive surgery.[22] Furthermore, an ex vivo experimental randomized study demonstrated that PLL reliably resisted physiologic and supraphysiologic airway pressures after lobectomy in canine cadavers weighing up to 35 kg.[22] The use of ligation clips has been described widely in both human and veterinary medicine for open and minimally invasive abdominal and thoracic surgery[20,21,25–27] and could also be considered for lung lobectomy in smaller dogs and cats. A study in a rabbit model evaluating the use of polymer ligating clips (Hem-o-lok) to seal the pulmonary hilus showed no differences in leak pressures when it was compared with surgical ligation.[20] This type of clip was also successfully used for VATS lung lobectomy in a small dog in a recent case report.[21] Titanium ligation clips have proven to be biocompatible and generate lower inflammatory reaction and lower tissue adhesions compared to the other ligation methods in a rodent model.[25]

A newly designed titanium double-shank (DS) ligation clip with two parallel and interconnected shanks has been used successfully for appendicular stump closure in appendectomy in human medicine.[25–27] The DS titanium clips compress tissue during closure, providing extra protection against axial displacement and ensuring a constant closing force. The double shanks also prevent clip scissoring, a known complication of single shank clips.[27] The diamond-shaped inner surface of the clips allows the tissue to sink in, increasing the contact surface of the tissue and ensuring a strong grip (Figure 1). The DS ligation clips are available with or without a latch at the tip; however, both types have the same closure mechanism. The latch may be of further benefit in cases of dealing with inflamed tissues as this also prevents tissue slippage.[26,27] The DS titanium clips are available in different sizes and clip appliers are provided for laparoscopic and open surgery.

As far as the authors are aware, the airway leak pressure of the PLL and DS titanium clips has not been experimentally evaluated in hilar lung lobectomy in cats. The objective of this study was to compare PLL and DS titanium clips with a thoracoabdominal (TA) linear stapler for complete sealing under physiologic and supraphysiologic airway pressures for total lung lobectomy in a feline cadaveric model. The hypothesis was that there would be no difference in leakage incidence between these devices up to a pressure of 40 cm H_2O.

2 | MATERIALS AND METHODS

2.1 | Animals

Before starting the study, ethical approval was granted by the animal welfare and ethical review body of the University of Nottingham (Approval number. 3711 221 109). All feline cadavers were donated for this research after

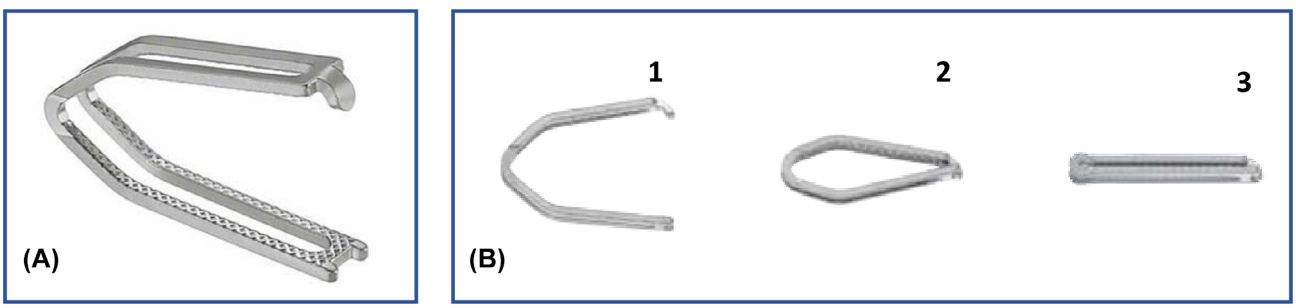

FIGURE 1 Double-shank (DS) clip with a latch (A), which also prevents the clip from slipping. Closing behavior of the clip (B).

written consent, including a description of the study, was obtained from their owners. Entire lung sets, including intact larynxes and tracheas, were harvested from five fresh feline cadavers, humanely euthanized for reasons unrelated to this study. Cats with a history of gross evidence of pulmonary disease were excluded from the study.

2.2 | Specimen preparation

Testing was performed immediately after euthanasia or following storage for less than 12 h at 4°C. Each lung lobe from every cadaver was randomly assigned to one of the three lobectomy techniques using an online randomization website (www.random.org), ensuring an equal total number of lobectomies for each technique. Ten lung lobes were randomly assigned to each of the three groups: group 1, linear stapler; group 2, PLL; and group 3, DS titanium clip. The hilus of each individual lung lobe, including bronchus and pulmonary vessels, was isolated to apply the surgical devices accordingly.

For the linear stapler group, a reloadable 30 mm vascular linear stapler (DST Series TA, Medtronic, Minneapolis, MN, USA) and TA30V3L cartridges (three-row staples, 2.5 mm length) were used according to the manufacturer's guidelines. The staple line was placed across the entire hilus, ensuring that the bronchus and both the pulmonary vein and artery were included, with the stapler positioned centrally. The lobe was then resected distal to the staple line using a no. 11 scalpel blade, with the stapler cartridge serving as a cutting guide. The stapler was disengaged and removed prior to leak testing.

For the PLL group, a single 0 USP polydioxanone PLL (Endoloop PDS II; Ethicon, Johnson & Johnson, Raritan, NJ, USA) was placed around the hilus by passing the encircling ligature over the lobe to include the bronchus and the pulmonary artery and vein *en bloc*. The loop was then tightened according to manufacturer guidelines, as previously described, and resected 5 mm distal to the ligature.[22]

For the DS titanium clip group, one large (L) DS titanium ligation clip with a latch (DS clip; B. Braun Aesculap, B. Braun Vet Care GmbH, Germany) was used following the manufacturer's guidelines. The clip was placed across the entire hilus, ensuring the inclusion of the bronchus and both the pulmonary vein and artery (Figure 2). The lobe was then resected 5 mm distal to the clip (Figure 3).

2.3 | Leak test

A 4.5 mm cuffed endotracheal tube (ET tube) was used for all feline cadavers. The cuff was inflated and a cable tie was placed around the trachea to create an airtight seal.[22] The endotracheal tube was connected to an anesthetic machine equipped with a mechanical ventilator. The ventilator was set to inflate the lungs to a peak inspired airway pressure of 15 cm H_2O, with a respiratory rate of 12 breaths per min,[16,28,29] and an inspiratory-expiratory ratio (I:E ratio) of 1:2. The lungs were submerged in water and assessed for leaks that may have occurred accidentally during lung harvesting. Immediately after each lung lobectomy, airway leak testing was conducted as described in previous studies by submerging the sealed bronchial stumps in water.[16,18,22,30] The peak inspired airway pressure was increased gradually, by 5 cm H_2O every five lung inspirations, from 15 cm H_2O up to 40 cm H_2O by gradual increase of tidal volume. If a leak was detected at the lobectomy site, the leak pressure was recorded, the affected bronchus was clamped, and the leak test was continued for the remaining bronchial stumps. If no leaks were observed when the pressure reached 40 cm H_2O, the pressure was held for at least 10 s and continued to be monitored for

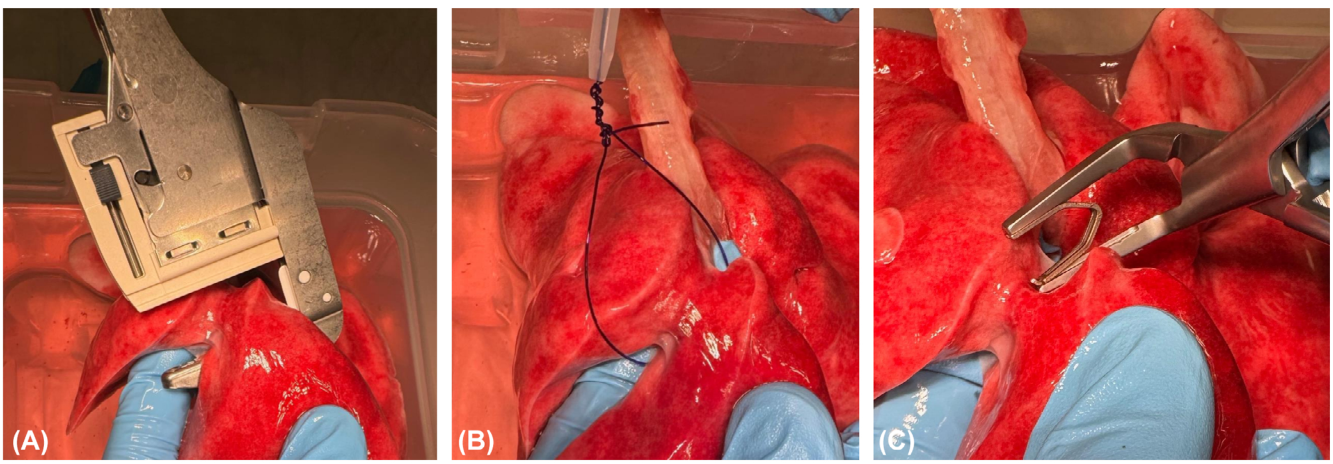

FIGURE 2 Positioning of the linear stapler (A), pretied ligature loop (B) and double-shank (DS) clip with a latch device (C) used for lung lobectomy before closure or tightening of the devices.

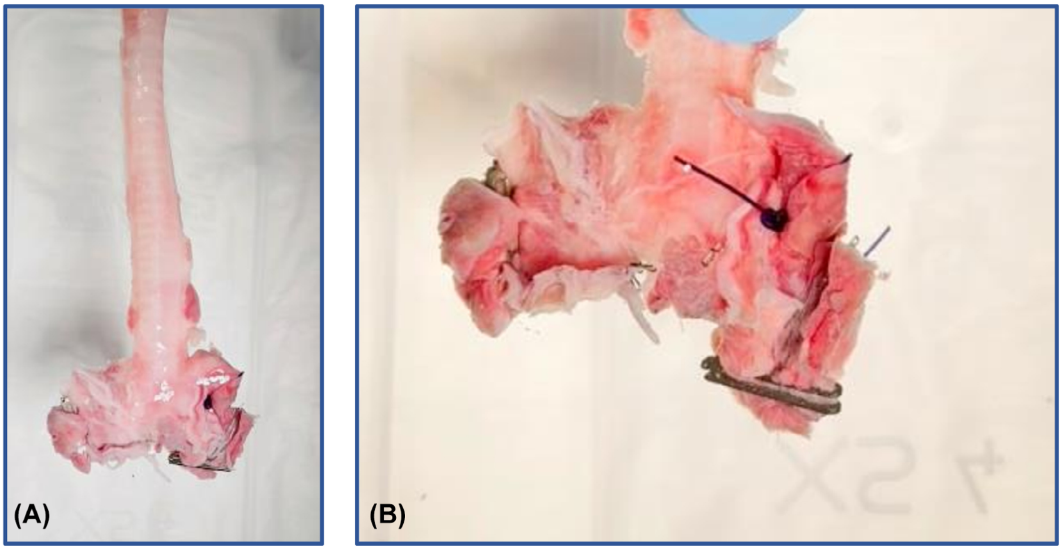

FIGURE 3 Each of the bronchial stumps after lung lobectomy with different ligation techniques.

signs of air leakage.[16] The presence or absence of a leak after the final pressure was reached was recorded.

2.4 | Statistical analysis

To compare the incidence of leakage across the three treatment groups (linear stapler, PLL, and DS clip), Fisher's exact test was performed. Statistical testing was performed with commercially available software (IBM SPSS Statistics for macOS, https://www.ibm.com/products/spss-statistics), and the significance level was set at $p < .05$. In the formulation of the study, a software tool (Genstat, VSN International Ltd.) was used for an a priori power analysis to determine the minimum sample size. The sample size was calculated with an alpha value of .05, a beta value of .1, and a power of 90%. Based on previously conducted studies by Cronin et al. and Sandoval[31] et al., and the recognition that a 0% complication rate in larger sample sizes was unrealistic, a 5% rate of air leakage complications for feline lung lobectomy was assumed across all three techniques. The calculation resulted in a sample size of six lungs per group. To account for potential issues during lung lobe harvesting, a final sample size of 10 lung lobes per group was considered.

3 | RESULTS

The lung sets were harvested from five domestic shorthair cats with a median body weight of 3.6 kg (range: 3.3–3.8 kg) and a median age of 14.8 years (range: 8.3–18.4 years). The harvesting of the lung sets, hilar lung lobectomies, and the leak tests were performed within a median of 100 min from euthanasia (range 65–135 min). Hilar lung lobectomy was performed without technical difficulties, regardless of the technique used. Details of the randomized lung lobe group distribution and outcomes are summarized in Table 1. In group 1 (linear stapler), 1 of 10 (10%) lobes leaked from the left caudal bronchus at a supraphysiologic pressure of 40 cm H_2O. Air leakage occurred at pinpoints along the staple line. No further leaks were observed in group 1. No leaks occurred in group 2 (PLL) and group 3 (DS titanium clip).

The Fisher's exact test compared the linear stapler group (nine successes, one failure) with the combined PLL and DS groups (20 successes, 0 failures), yielding a p value of .333, indicating no difference in leakage incidence between the groups.

4 | DISCUSSION

This is the first ex vivo comparative randomized study evaluating three different techniques for achieving complete sealing under physiologic and supraphysiologic airway pressures following hilar lung lobectomy in a feline cadaveric model. The results of this study supported the hypothesis that there would be no difference in air leakage incidence among the linear stapler, PLL, and DS clips up to a pressure of 40 cm H_2O. These results suggest that PLL adn DS clips may be viable alternatives to linear staplers for hilar lung lobectomy; however, further studies are needed to confirm their safety and efficacy.

Feline patients with normal lungs typically require low peak inspiratory pressures, ranging from 8 to 15 cm

TABLE 1 Group randomization and outcomes.

Lung lobe	Lung set #1	Lung set #2	Lung set #3	Lung set #4	Lung set #5
Right cranial	Endoloop	TA staple	TA staple	Endoloop	Endoloop
Right middle	Endoloop	TA staple	DS clip	DS clip	Endoloop
Right caudal	TA staple	DS clip	Endoloop	TA staple	TA staple
Accessory	DS clip	Endoloop	TA staple	Endoloop	DS clip
Left caudal	TA staple	DS clip	DS clip	DS clip	TA staple[a]
Left cranial	DS clip	Endoloop	Endoloop	TA staple	DS clip
Failure rate	0/6	0/6	0/6	0/6	1/6

Abbreviations: DS, double shank; TA, thoracoabdominal.

[a]Left caudal bronchus sealed with a TA staple leaked at a supraphysiologic pressure of 40 cm H_2O.

H_2O.[29] Setting the maximum peak inspired airway pressure to 40 cm H_2O, the study subjected the sealed bronchial stumps to up to five times the physiologic airway pressure, in accordance with previous experimental methods.[13,16,18] By using supraphysiologic pressure (40 cm H_2O), the aim was to test the limits of these sealing devices withstanding stress beyond normal physiologic levels, ensuring they can perform reliably in unforeseen scenarios. This can be particularly relevant when unexpectedly high peak pressures may occur due to pathological conditions that increase airway resistance (e.g. airway obstruction, severe pulmonary pathology) or intrathoracic pressure (e.g., pneumothorax, coughing, vomiting). Moreover, the leak test of this study was performed in a cyclic (inspiration/expiration) manner, which has the dual advantages of better simulating the clinical scenario and evaluating the integrity and holding strength of the devices at the level of the bronchial stumps.

All PLL and DS clips completed testing without failure, and only one of the TA stapled lobectomies leaked at a supraphysiologic inspired airway pressure of 40 cm H_2O. The vascular cartridges used in this study contain three staggered rows of 2.5 mm long staples, which uniformly compress tissues to 1.0 mm. Shorter staple lengths have been shown to achieve better hemostasis and pneumostasis.[32] However, pinpoint leaks can occur at staple insertion points[18] and this was observed in a single case in the study.

The hilar lung lobectomies were performed by the same investigators, all experienced in the stapling technique. It is possible, however, that in this single case, the staple line could have not been placed exactly at the hilus. Stapling more than 5 mm from the hilus was identified as a crucial factor for air leakage in a study comparing a resorbable self-locking ligation device with TA55 3.5 mm staples in a thoracoscopic-assisted lung lobectomy in cat cadavers.[16] This finding emphasizes the importance of obtaining adequate access to the pulmonary hilus, which can be challenging in a constrained thoracic cavity. The limitation of stapling devices in such scenarios highlights the benefits of more maneuverable instruments, such as the PLL and DS clip. It is noteworthy that lung sets with gross evidence of pulmonary disease were excluded from this study. In a clinical setting, the presence of lung pathology could impair appropriate hilar device placement, increasing the risk of bronchial leakage and hemorrhage.

The PLL is widely used in human surgery, including partial lung lobectomy,[33] appendicectomy,[34] and salpingo-oophorectomy.[35] In veterinary medicine, its use has been described for lung lobe biopsy,[12] total lung lobectomy in ex vivo studies,[22] clinical case series,[22] and partial and total liver lobectomy.[36,37] The negative leak test recorded in the PLL group in the current study aligns with previous studies, such as an investigation by Cronin et al., who successfully used PLL for canine lung lobectomies.[22]

Double-shank clips are commonly used in human medicine for appendicectomy,[25] both in open and laparoscopic approaches.

A study comparing the results of minimally invasive appendectomies performed using a linear stapler, DS clip, and invaginating sutures, revealed that the shortest hospitalization and lowest complication rates occurred in patients treated with DS clips.[38] Although the diameter of the main bronchus for each lung set was not measured in this study, as it was beyond its scope, a study by Panopoulos et al. reported mean diameters for the bronchial and pulmonary vascular structures in domestic shorthair cats based on CT assessments. In that study, cats had a median body weight of 4.3 kg (range 2.7–6.7 kg). The mean bronchial diameters were 3.77 mm for the right cranial lobe, 2.21 mm for the right middle, 2.12 mm for the accessory, 3.9 mm for the right caudal, 3.21 mm for the left cranial, and 3.83 mm for the left caudal lung lobe.[39]

There are no established guidelines for size selection of the DS ligation clip for hilar lung lobectomy. In this study a large DS clip (12.6 mm in length and 10.3 mm in width) sealed the main bronchus successfully in all lobes. As the bronchus and vessels are gradually compressed and simultaneously flattened during the clip's closure, the large-sized DS clip was used to anticipate potential lateral elongation or “pushing out” of the tissue and to ensure safe lateral margins within the clip. The presence of a latch at the tip of the clip provides additional security for axial dislodgement,[26,27] making the DS ligation clip with a latch more suitable for tissues such as the bronchial stump, which undergo continuous motion and cyclical stress. However, a comparison between the DS ligation clips with and without latch was beyond the scope of this study.

Severe inflammation or enlargement of the hilar base is a potential challenge associated with the use of PLL and DS titanium clips. This may complicate effective clip closure. In such cases, using a stapler could provide a safer option for achieving bronchial closure and hemostasis, as indicated in humans for appendicectomy.[40] However, this may be of less concern in feline patients due to their smaller anatomical size.

There are several limitations to this study, including the restricted sample size, its cadaveric nature, the absence of pulmonary disease, unaccounted individual anatomic variability, and the relatively short cyclic test design. Although a power analysis was conducted to estimate the required sample size, the final number of 30 lung lobes (10 per group) remains relatively small. Increasing the sample size would enhance the statistical power of the study, potentially reducing the risk of Type II error and yielding more statistically significant findings. The cadaveric nature of the study is an inherent limitation as a cadaveric model cannot fully replicate live conditions, such as hemodynamic responses or the respiratory mechanics of living animals. The absence of these factors might limit the ability to simulate the actual challenges faced during surgery and may influence the performance of the devices tested. The use of cadavers limits the adequate assessment of hemostasis as well as the long-term outcomes that would be observed in living animals. The exclusion of cats with pre-existing pulmonary pathology limits the study's application to all clinical scenarios in which patients may present with underlying pulmonary diseases, which could influence the performance of the devices tested. Individual bronchial and vascular anatomical variability could affect the devices' performance and further studies in a broader live population may help mitigate this factor. Furthermore, the performance of these ligation devices was only evaluated over a short cyclic leak test. Tests over longer cyclic pressures, which would better represent clinical scenarios, might impact the devices' safety and effectiveness over time.

In conclusion, the linear stapler, PLL, or DS titanium clips were equally effective at sealing the hilar lung lobectomy site under a maximum airway pressure of 40 cm H_2O in this ex vivo feline study. The PLL and DS titanium clips are relatively easy to use, even by surgeons with limited experience, require less working space and may represent a viable alternative to traditional stapling devices in open and minimally invasive feline pulmonary lobectomy. Based on the findings of this study, further clinical evaluation of these devices is warranted to assess their efficacy, appropriate case selection, and potential short- and long-term complications. Further in vivo studies are also required to confirm these findings under both physiological and pathological conditions and to help translate the experimental model results into clinical application. However, obtaining ethical approval for such prospective studies may represent a limiting factor.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest related to this report.

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article and its Supporting Information.

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