In vivo comparative assessments on pleural adhesive effects of three commercially available sealants

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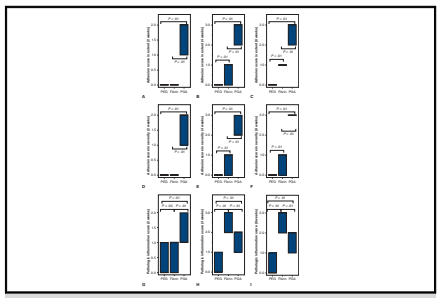
ABSTRACT

Objective: Surgical sealant, which is used for the reinforcement of suture lines, has been widely used in lung-resection surgeries with the aim of reducing postoperative morbidity; however, it may exacerbate surgical-site adhesion, creating the risks of restrictive thoracic movement and a difficult entrance for redo operation. We aimed to assess the pleural adhesive effects of 3 frequently used surgical sealants, (1) fibrin glue (fibrin), (2) a composite of polyethylene glycol and human serum albumin (PEG/HSA), and (3) bioabsorbable polyglycolic acid felt (PGA), in an in vivo setting.

Methods: Eighty-one rats were randomly assigned to 3 experimental groups—fibrin, PEG/HSA, and PGA. After intrapleural application of the sealants, the extent and severity of adhesion and inflammation were quantitatively compared among the 3 groups at 2, 4, and 8 weeks.

Results: The scores for both the extent and severity of adhesion were significantly greater in the PGA group than the other 2 groups throughout postoperative period ($P < .001$ for all). Although both scores in the PES/HSA and fibrin groups were 0 at 2 weeks, the fibrin group showed significantly greater scores than the PES/HSA group thereafter ($P < .001$ for all). Trends in inflammation scores were similar of those of adhesion scores, favoring the PES/HSA group followed by the fibrin group ($P < .001$ for all).

Conclusions: Among 3 commonly used sealants, PEA/HSA showed least degree of adhesion/inflammation compared with fibrin and PGA, whereas PGA demonstrated greatest degrees of adhesion/inflammation throughout a postoperative course of 8 weeks in an in vivo model. (JTCVS Techniques 2024;26:131-8)



Box plots showing the adhesion score and severity of the pathologic inflammation score.

CENTRAL MESSAGE

The degree of adhesion/inflammation of 3 commonly used sealants was compared through an in vivo model. PEA/HSA showed the least degree of adhesion/inflammation compared with fibrin and PGA.

PERSPECTIVE

Our results show that PEG/HSA has theoretical advantages over other materials in patients with impaired lung function with respect to the high risk of recurrent chest surgery or minimal adhesion formation and the most adaptive lung dilatation.

In lung-resection surgery, resection margins are a major source of postoperative air leaks; hence, the buttressing of such suture or staple lines is a widely used practice to mitigate postoperative air leakage. For this, a number of sealants have been developed and used in practice, and among them, 3 commercially available sealants—a polyglycolic acid (PGA) sheet, fibrin glue (fibrin), and polyethylene glycol and human serum albumin (PEG/HSA)—can be considered the most commonly used, and their efficacy has been demonstrated in a number of studies.[1-7] PGA is generally a wound surface–covering agent reinforcing the wounds or suture lines effective for secondary healing.[8,9] Fibrin is composed of human fibrinogen and human thrombin in separated chambers, which form a cross-linked gelatin mixture by hydrogen bonding once they are exposed to each other on the applied surface.[5,10] PEG/HSA

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Received for publication March 4, 2024; revisions received April 8, 2024; accepted for publication April 12, 2024; available ahead of print April 20, 2024.

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https://doi.org/10.1016/j.xjtc.2024.04.007

Abbreviations and Acronyms
PEG/HSA = polyethylene glycol and human serum albumin
PGA = polyglycolic acid

polymerizes to form a flexible, cross-linked hydrogel matrix that adheres to lung tissue and allows it to stretch as the lung is reinflated.[2,11]

Among potential pitfalls of these sealants is adhesion formation in the pleural cavity.[8,12-15] Pleural adhesion, with intensifying extent and severity, is known to cause restrictive thoracic movement, chronic chest pain or discomfort, and consequent prolonged hospitalization and increased incidence of hospital readmissions. In addition, redo operation, not-infrequent episodes in thoracic oncologic surgeries, can be challenging in the presence of pleural adhesion because of difficult entrance to the pleural cavity, poor exposure of the operative fields, and a long operative time.

In these regards, research on comparative effects on pleural adhesion among these widely used commercially available sealants is important to optimize the selection for lung-resection surgery. In the present study, therefore, we sought to assess the pleural adhesive effects of 3 frequently used surgical sealants, fibrin, PEG/HSA, and PGA, in an in vivo setting.

METHODS

Animals

Nonpregnant 8-week-old female Sprague-Dawley rats weighing approximately 200 g were used for the experiments. All rats were housed separately and maintained under standard specific pathogen-free conditions (light-dark cycle: 12:12 hours, mean temperature: 23 °C, and mean humidity: 50%). Standard laboratory rodent chow and water were available ad libitum. On the day of the experiment, the health status of all rats was checked (diarrhea, unusual fur [loss or dirtiness], mucous discharge from the eyes or anus, and emaciation). The Pusan National University Hospital Animal Experimentation Committee approved the experiment (PNUH-2023-214) on February 7, 2023, and all surgical procedures and anesthesia protocols were conducted in accordance with the Animal Care Guidelines of Busan National University Hospital.

Experimental Design

Eighty-one rats were randomly assigned to 3 experimental groups—fibrin, PEG/HSA, and PGA—with 27 rats in each group. Within each group, rats were further randomly allocated into 3 subgroups (9 in each) so that they could be examined by surgical re-exploration at 3 different time points of 2, 4, and 8 weeks' postoperatively.

The adhesive effects and the inflammatory changes of the applied areas were compared among the fibrin, PEG/HSA, and PGA groups at each period. The extent and severity of adhesion were graded on the basis of the adhesion grading scale, and inflammation scores were also recorded according to the histologic scoring system (Table 1).

TABLE 1. Category and description of adhesion and inflammation

Category and description	Score
Macroscopic	
Extent	
No involvement	0
≤25 mm of the site involved	1
≤50 mm of the site involved	2
≤75 mm of the site involved	3
≤100 mm of the site involved	4
Severity	
No adhesion present	0
Adhesions fall apart	1
Adhesions can be lysed with traction	2
Adhesions requiring dissection	3
Microscopic	
Histologic scoring system of inflammation	
Normal	0
Mild Inflammatory infiltration	1
Moderate inflammatory cells infiltration	2
Moderate-to-severe inflammatory cells infiltration	3

Materials and Surgical Technique

All operations were performed under sterile conditions and by a single surgeon (H.Y.A.). Rats inhaled 5 mg of sodium pentobarbital diluted in 1 mL of physiological saline solution. Under general anesthesia, rats, fixed in the dorsal position, received a 2-mm horizontal incision along the rib. The 6-French Nelaton catheter (width, 2 mm) designed to cut in one third to reduce internal dead space was placed at the apex of the right lung

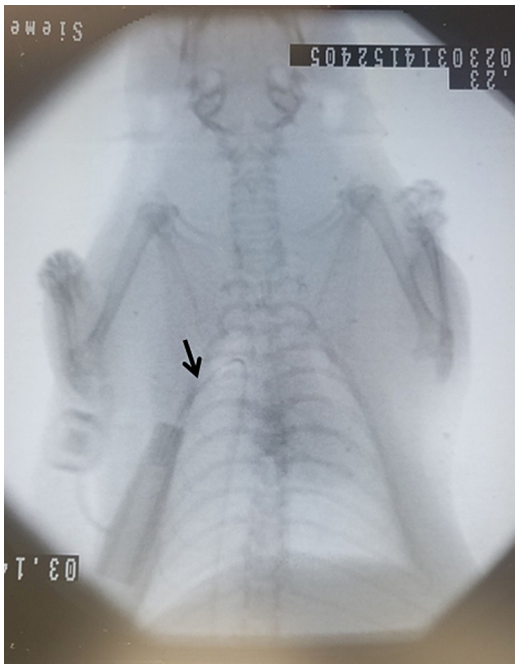

FIGURE 1. Radiograph of a rat from our study. The tip of catheter (*arrow*) can be seen at the apex of the right lung.

TABLE 2. The adhesion extent, severity scores, and inflammation scores

Sealants	PEG/HSA	Fibrin	PGA	*P* value
Adhesion extent, wk				
2	0.00	0.00	1.67 ± 0.57	<.01
4	0.00	0.67 ± 0.58	2.67 ± 0.57	<.01
8	0.00	1.00 ± 0.00	2.67 ± 0.58	<.01
Adhesion severity, wk				
2	0.00	0.00	1.67 ± 0.58	<.01
4	0.00	0.67 ± 0.58	2.33 ± 0.58	<.01
8	0.00	0.67 ± 0.58	3.00 ± 0.00	<.01
Inflammation, wk				
2	0.33 ± 0.58	0.67 ± 0.58	1.33 ± 0.58	<.01
4	0.67 ± 0.58	2.33 ± 0.58	1.67 ± 0.58	<.01
8	0.67 ± 0.58	2.67 ± 0.58	1.67 ± 0.58	<.01

PEG/HSA, Polyethylene glycol and human serum albumin; *PGA*, polyglycolic acid.

through the incision, which could be viewed by a C-arm radiographic examination (Figure 1).

Fibrin (TISSEEL; Baxter Healthcare Corp) and PEG/HSA (Progel; Bard Davol) were used according to the manual provided by the manufacturer in the form of 2 mixtures. Fibrinogen (0.5 cc) and thrombin (0.5 cc) of the fibrin group, and human serum albumin (0.5 cc) containing PEG cross-linker (0.5 cc) of the PEG group both in separated chambers were alternately dropped to allow the combination at the lung surface in the apex, which was followed by a small amount of air injection to remove the remaining material in the catheter. PGA (NEOVEIL; Gunze Medical) was cut into square sheets, 5 mm × 5 mm in size, and rolled up to administer using a sharp mosquito through a 2-mm incision on the chest wall. The incision was repaired with 4/0 polyvinylidene fluoride monofilament sutures.

Assessment of Adhesion Effect

We classified adhesion extent into 5 grades on the basis of a modified version of the classification system reported by Tsujimoto and colleagues[16]: grade 0, no adhesions; grade 1, ≤25 mm of the site involvement; grade 2, ≤50 mm of the site involvement; grade 3, ≤75 mm of the site involvement; grade 4, ≤100 mm of the site involvement. We classified adhesion severity into 4 grades, as described previously: grade 0, no adhesions; grade 1, adhesions fall apart; grade 2, Adhesions can be lysed with traction; and grade 3, Adhesions requiring dissection.

Pathologic Examination

After evaluating the adhesion extent and severity at 2, 4, and 8 weeks, we excised the lobe covered with materials and immersed them in 10% formalin. We performed hematoxylin-eosin staining to evaluate severity of inflammation. We classified inflammation into 4 grades on the basis of a modified version of histologic scoring system of inflammation reported by Passmore and colleagues[17]: grade 0, no inflammation; grade 1, mild inflammatory infiltration; grade 2, moderate inflammatory infiltration; grade 3, mild inflammatory infiltration; grade 4, moderate-to-severe inflammatory infiltration.

Statistical Analysis

The statistical analyses were performed using R Studio, Version 2023.12.0 (R Foundation for Statistical Computing). All parameters are reported as mean ± standard deviation. To compare adhesion scores (extent and severity) and microscopic inflammation in the 3 groups, the Levene test for equality of samples was used and a one-way analysis of variance with a Tukey post hoc test was followed.

RESULTS

There were no cases of mortality or complications before re-exploration for examinations.

Macroscopic Findings of the Adhesive Effects

Regarding the severity of adhesion, the PEG/HSA group showed scores of 0 in all cases throughout 2 to 8 weeks, whereas PGA group showed the highest scores of 1.67 ± 0.58, 2.33 ± 0.58, and 3.00 ± 0.00 at 2, 4, and 8 weeks, respectively, which were significantly greater than those in the fibrin and the PEG/HSA groups ($P < .01$ for all; Table 2; Figure 2). At 2 weeks, the scores for extent and severity of adhesions were not significantly different between the fibrin and the PEG/HSA groups; however, they were significantly greater in the fibrin group than the PEG/HSA group thereafter ($P < .001$ for all; Table 2, Figure 2).

Gross and Pathologic Inflammation Scale

Gross appearance of the affected pleural cavity in the PGA group at 8 weeks indicated tight fibrous capsule formation between the visceral pleura and right atrium (Figure 3, *F*), which could not be dissected by traction. In the fibrin group, we observed loose filmy adhesion partially covering the affected areas at 4 weeks (Figure 3, *C*), after which multiple linear adhesion bands were observed at postoperative 8 weeks (Figure 3, *D*). No cases in the PEG/HSA group, however, showed any sign of gross adhesion formation (Figure 3, *A* and *B*).

Pathologic study at 2 weeks in the PGA group showed the pathologic inflammation score of 1.33 ± 0.58, which was significantly greater than the score of 0.67 ± 0.58 in the

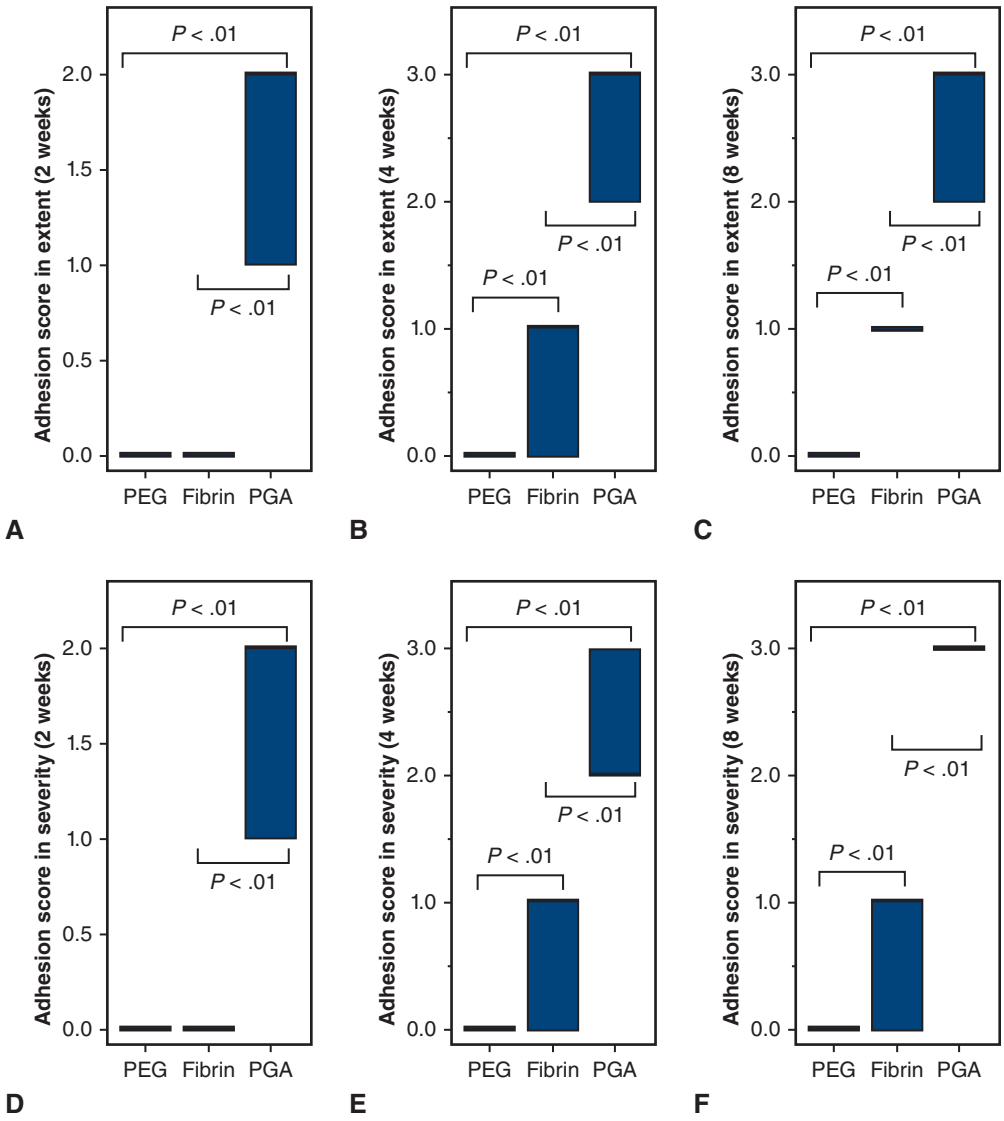

FIGURE 2. Box plots showing adhesion scores after 2 weeks (A), 4 weeks (B), and 8 weeks (C) and the severity after 2 weeks (D), 4 weeks (E), and 8 weeks (F) after application of fibrin glue, polyethylene glycol and human serum albumin (*PEG/HSA*), and polyglycolic acid (*PGA*), respectively.

fibrin group ($P < .01$; Table 1; Figure 4). The fibrin group, however, showed the greatest scores of 2.33 ± 0.58 and 2.67 ± 0.58 at 4 and 8 weeks, respectively, which were significantly greater than those in the PGA and the PEG/HSA groups (Figure 4). Only in the PGA group, a foreign body reaction was found throughout 2 to 8 weeks, and at 8 weeks, tight adhesion between visceral and parietal pleurae hindered dissection of the pleural space (Figure 5, *C*, *F*, and *I*). In the PEG/HSA group, in contrast, the pathologic inflammation scores were as low as 0.33 ± 0.58, 0.67 ± 0.58, and 0.67 ± 0.58 at 2, 4, and 8 weeks, respectively, which were significantly lower than those in the fibrin and the PGA groups ($P < .01$ for all; Table 2; Figure 5, *B*, *E*, and *H*).

DISCUSSION

The present study evaluated the pleural adhesive effects of 3 commercially available sealants—fibrin, PEG/HSA, and PGA—in an in vivo setting and demonstrated that the use of PEG/HSA showed lower degrees of pathologic inflammation and adhesion in the pleural cavity as compared with fibrin and PGA. There have been a number

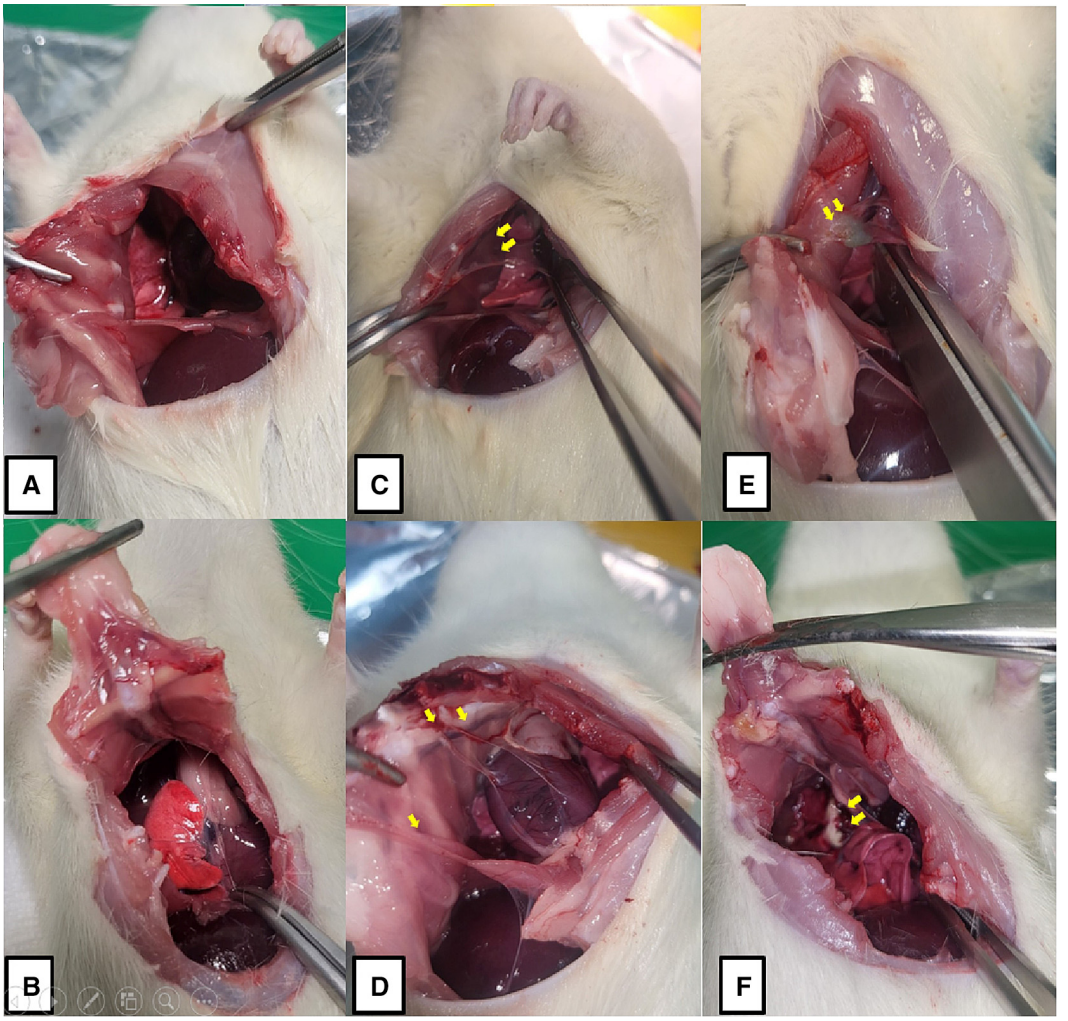

FIGURE 3. Gross intraoperative findings. Shown are the polyethylene glycol and human serum albumin (PEG/HSA) group (A and B), fibrin glue (fibrin) group (C and D), and polyglycolic acid (*PGA*) group (E and F) at 4 weeks (A, C, E) and 8 weeks (B, D, F) after application, respectively. C, Diffuse adhesion (*arrow*) can be seen. D, Multiple linear adhesion band (*arrow*) exists. A and B, No adhesion. E, Strong adhesion (*arrow*) has developed between the parietal pleura and the lung. F, The strong adhesion aggravated the foreign body reaction (*arrow*) over 8 weeks, which could be seen between the visceral pleura and right atrium.

of studies on surgical materials that may inhibit adhesion formation in the setting of sealant applications. Matoba and colleagues[18] demonstrated that antiadhesive effects of noncross-linked alginates were effective for preventing PGA-induced adhesions. Takagi and colleagues[19] presented a comparable antiadhesive effect of the material composed of aldehyde dextran and ε-poly powder to prevent the postoperative pleural adhesion. The basic premise of these studies entails the substantial adhesive effects in most commercially available sealants for thoracic surgery, and therefore, assessments of the sealants on pleural adhesive effects per se are also clinically important.

The strengths of this study include providing a comprehensive view of the extent and severity of pleural adhesion and pathologic lung inflammation induced by the sealants. In particular, the severity of adhesion in the PGA group showed the greatest scores throughout 2- to 8-week time points, which were significantly greater than those in the fibrin and the PEG/HSA groups, and parietal pleura adhered tightly to the visceral pleura at 8-week point that could not be dissected by traction. As the hydrolysis of PGA to glycolide results in the inflammatory responses in implanted tissues,[20] a substantial level of inflammation found in histologic examinations of lung tissue in the present study correlates well with its underlying action mechanism PGA (Figure 5, *I*).

Meanwhile, the pathologic inflammation scores in the fibrin group showed the greatest scores at 8 weeks, which

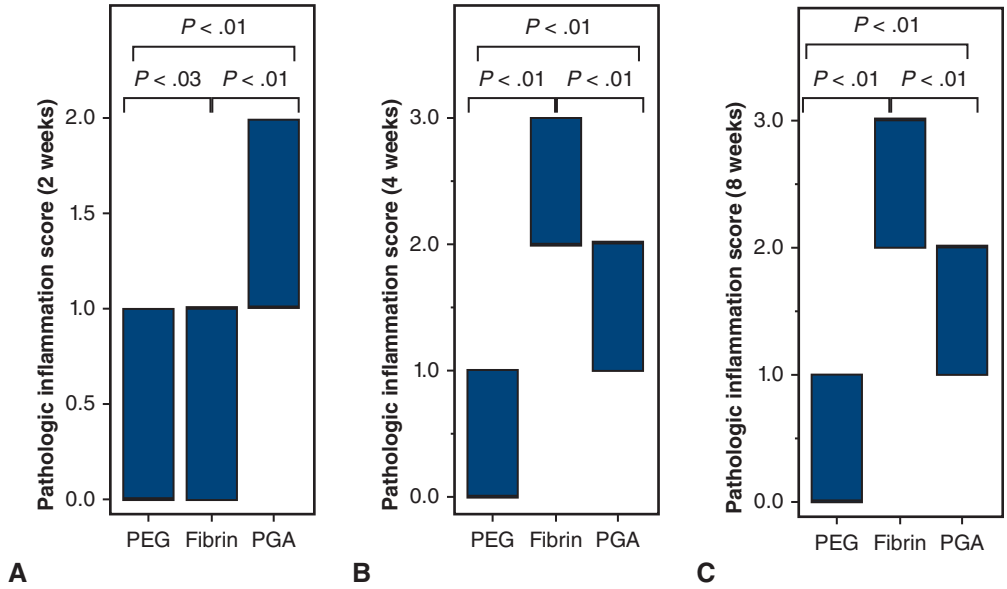

FIGURE 4. Box plots showing the pathologic inflammation score after 2 weeks (A), 4 weeks (B), and 8 weeks (C) after application of fibrin glue, polyethylene glycol and human serum albumin (*PEG/HSA*), and polyglycolic acid (*PGA*), respectively.

was even greater than those in the PGA group (Table 2, Figure 4). This seems to not correlate with the lower levels of adhesion formation of the fibrin group as compared with the PGA group at this time point. One previous study, however, demonstrated similar results with those of the present study that a fibrinogen/thrombin compound only induces a pronounced local inflammatory response to lung parenchyma, promoting tissue healing but without leaving significant residual adhesion.[21]

In contrast, the severity of adhesion in the PEG/HSA group showed scores of 0 in all cases throughout 2- to 8-week time points, and no cases showed a sign of gross adhesion formation. Moreover, the pathologic inflammation scores throughout 2- to 8-week time points were significantly lower than those in the fibrin and the PGA groups.

This may be explained by the reversible dynamic mechanics of PEG/HSA in that PEG hydrogel gives rise to adhesions only in contact with moist, deformable tissue while the hydrogel becomes flexible at elevated pH of human body ranges.[22,23] Attributed to these bimodal mechanisms of PEG/HSA, it maintains a highly compliant and flexible feature while offering sealant/adhesive capacities on the lung surface. Furthermore, PEG hydrogel coating is known to shield the biomaterial surface and thereby passively restrict complement activation to prevent inflammation.[22] These working mechanisms of PEG/HSA might have contributed to minimum levels of inflammation and adhesion in the present study. On the basis of the study findings, PEG/HSA seems to have theoretical benefits over other materials in patients with high risks of repeated thoracic surgeries, or with impaired lung function in the respect of least adhesion formation and most compliant lung expansion.

Limitations

The results demonstrated by the present experiment are derived from a rat model, and therefore, the reproducibility of the findings should be further validated by human clinical trials. Because of the lack of assessing the efficacy of air leak in this model, further studies should be followed to evaluate the differential air-sealing effects of the sealants.

CONCLUSIONS

Among 3 commonly used sealants, PEA/HSA showed the least degree of adhesion/inflammation compared with fibrin and PGA, whereas PGA demonstrated the greatest degree of adhesion/inflammation throughout a postoperative course of 8 weeks in an in vivo model.

Conflict of Interest Statement

The authors reported no conflicts of interest.

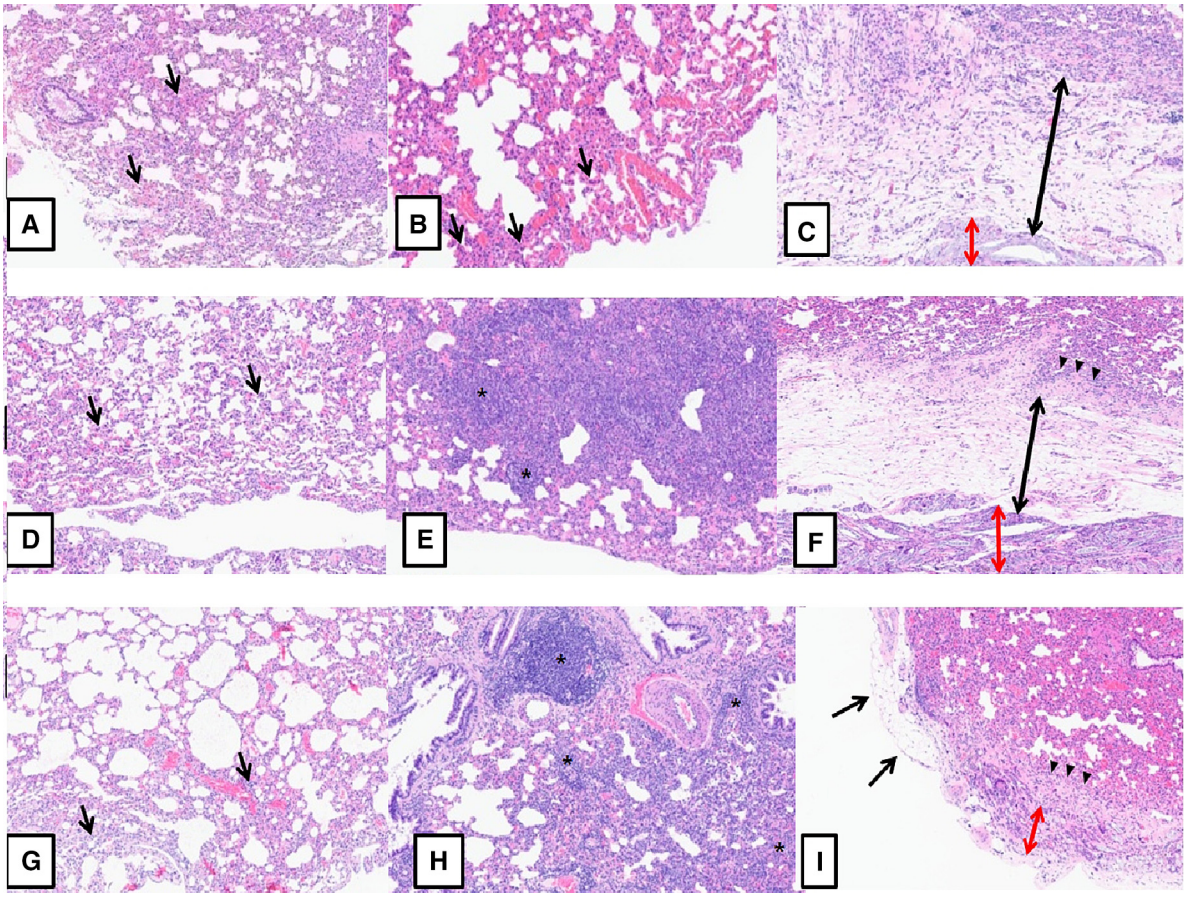

FIGURE 5. Hematoxylin-eosin staining of lung tissue. Original magnification ×40. Shown are the polyethylene glycol and human serum albumin (*PEG/HSA*) group (A, D, G), fibrin glue group (B, E, H), and polyglycolic acid (*PGA*) group (C, F, I) at 2 weeks (A, B, C), 4 weeks (D, E, F), and 8 weeks (G, H, I) after application, respectively. PEG/HSA group: (A, D, G) few inflammatory cells infiltrated, without any differences among time differences. Fibrin glue group: (B) mononuclear inflammation cells are infiltrated. E, Diffuse inflammatory cells and multinucleated giant cells (*asterisk*) are infiltrated. H, A large number of diffuse inflammatory cells and multinucleated giant cells (*asterisk*) are infiltrated. PGA group: (C) a foreign body reaction (*red double-headed arrow*) formed in response to the introduction of exogenous material, and amorphous materials are filled (*black double-head arrow*) between the foreign body reaction and visceral pleura with slight infiltrated lymphocytes (*arrow*). F, Mononuclear inflammation cells infiltrate around thickened visceral pleura (*triangles*). I, A foreign body reaction (*red double-head arrow*) allowed parietal pleura (*arrow*) to be stuck together and visceral pleura (*triangle*) be thicker.

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Key Words: sealants, postoperative adhesion, lung resection