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Primary results of chest wall reconstruction with Polydioxanone mesh on animals

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Abstract. – BACKGROUND, With the development of surgical techniques and biomedical material, increasing synthetic materials are applied to the chest wall reconstruction, such as autologous rib, muscle flap, bovine pericardium and sheet metal.

AIM, To detect the safety and efficiency of synthetic material Polydioxanone (PDO) in chest wall reconstruction.

MATERIALS AND METHODS, Healthy adult mongrel dogs operated with PDO, and then some clinical data were collected.

RESULTS, Here we showed that PDO mesh could close down the function of chest wall defect, and PDO mesh could be degraded gradually and forms a fibrous layer with the surrounding tissues. Our data further demonstrated PDO mesh leads to slight lung adhesion with a small shrinkage.

CONCLUSIONS, These findings thus provide the first evidence that the feasibility of PDO mesh in chest wall reconstruction in dogs.

Key Words:

Chest wall reconstruction, Synthetic material, PDO mesh.

Introduction

With the development of surgical techniques and biomedical material, the safety and efficiency of chest wall reconstruction has been improved significantly, yet the operation is still challenging[1-2]. The surgical operation aims to reconstruct sustained chest wall, stabilize thoracic and close pleural cavity, thus restoring normal breathing, alleviating pain, as well as avoiding respiratory insufficiency and thoracic cavity infection. The importance of reconstruction materials is highlighted by the development and requirement of the reconstruction operation.

At present, many kinds of materials can be applied to the chest wall reconstruction, such as autologous rib, muscle flap, bovine pericardium, sheet metal, etc. Synthetic material is convenient for clinical application due to its commercialized production, guaranteed source and quality. Besides, the synthetic material can be cut and processed during operation. At the same time, the clinical advantage of synthetic material is further determined by its diversity, durability, internal inertness and translucency to x-rays[3]. Therefore, synthetic materials like polypropylene, polyester, polyglactin, polytetrafluoroethylene and composite synthetic materials (mesh and methyl methacrylate sandwiches) have been widely applied in clinical and have achieved good results. However, reports also indicate that chest wall reconstruction with synthetic materials may result in risks and complications such as graft infection, mesh displacement, corrosion, hemorrhage, pleural adhesions, chronic pain and rigidity[3-5]. Clinical treatment of these complications is not easy, and the graft needs to be removed in serious condition, leading to a second operation or poor tissue healing. As a result, some surgeons concern about the application of the artificial synthetic material. Surgeons has realized that, during chest wall reconstruction the organism is implanted with exogenous synthetic material, producing exogenous reaction and the fiber generation reaction[6]. The fibrosis scar tissue can stabilize the chest wall with mechanical strength, but it leads to chest wall stiffness, chronic pain, and discomfort to different degrees and in diverse ranges after operation. It is meaningful to develop surgical material that can provide sufficient mechanical support in chest wall reconstruction and cause less harm and fewer complications to the organism in clinical application.

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Polydioxanone (PDO), biodegradable synthetic material, is characterized of high initial strength and moderate modulus together with good ductility and flexibility. Besides, the slow degradation speed and good biocompatibility enable PDO to maintain longer mechanical strength and reduce exogenous reaction in the organism, respectively[7-8]. Finally, PDO has been successfully developed into medical suture, widely used in clinic. In recent years, with the improved understanding of the material and the development of technology, the material is gradually developed into stent, sheet, patch, plate, pin and scaffold, which is successfully used in clinic and the study of tissue engineering[9-11]. Considering the excellent mechanical properties and long degradation time of PDO, we weaved the PDO monofilament into surgical patch with certain intensity and shape through a special method, tried to apply it into reconstruction of chest wall and observed the effect.

Materials and Methods

Preparation and Basic Properties of PDO

PDO mesh was provided by Donghua University (Figure 1). The 10 cm wide surgical patch, with 0.2 mm average pore diameter, 2600/N tensile strength as well as 2500/N burst strength, was weaved from PDO monofilament (0.18 mm, SANYO, South Korea).

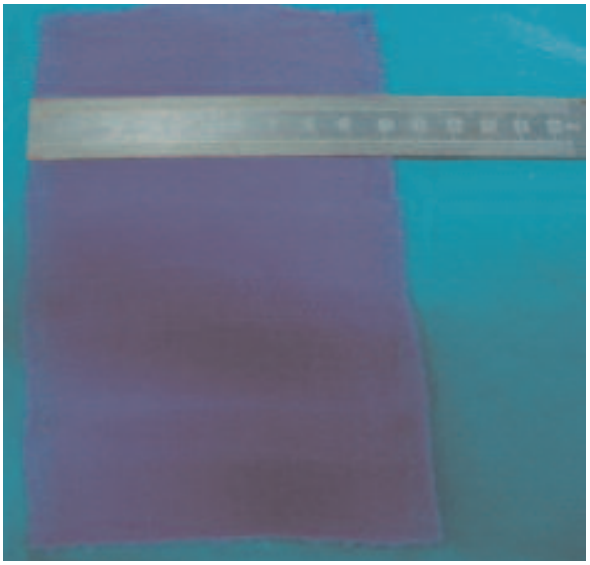

Figure 1. The mesh made of PDO material.

Preparation of Animals

15 healthy adult mongrel dogs of either sex, aged 2~3 years, weighing 23~25 kg, were included in this study. 9 of them operated with PDO were taken as research group and 3 with polypropylene (PP) as control group. All animals have received human care in compliance with the 1996 "Guide for The Care and Use of Laboratory Animals" and approved by the Institutional Animal Care and Use Committee at the Tongji Hospital, Tongji University. They all had free access to food and water, and were cared by an educated keeper and inspected by a veterinarian.

Dogs fasted after 21:00 on the eve of surgery. Anesthesia was first induced with intramuscular injection of ketamine hydrochloride (10 mg/kg i.m.) and then maintained with intravenous injection sodium pentobarbital (30 mg/kg i.v.) throughout the procedure. After tracheal intubation (respiratory rate 22-25 times per min, tidal volume 20-25 ml/kg), the dogs were placed in the left lateral position with fixed limbs, then the hair of the surgical zone was shaved, sterilized and bespreaded. The SaO_2 and heart rate was monitored during the surgery.

A 10 cm U-shaped incision paralleled with the costa near the sixth to eighth costal area was made on right chest wall. The serratus anterior muscles and the latissimus dorsi were separated anatomically through platysma muscles and subcutaneous tissue, and 6, 7, 8 ribs were exposed. The 8 cm segments of the consecutive three ribs were resected[5], including the intercostal muscle and the parietal, and the opening thoracic cavity with a 8 cm×8 cm chest wall defect was produced. Intercostal neurovascular bundle was carefully separated, ligated or cut off. Holes were pre-drilled at both ends of the 6, 7, 8 broken ribs, and the POD mesh was cut with ultrasonic scalpel to obtain a perfect size which accords with defect shape of the chest wall. The POD mesh was then placed in the defected chest wall, weaved by a running suture in absent of tension, and fixed in the intercostal muscles, intercostal space and ribs (Figure 2). No leakage occurred after blowing lung. Following hemostasis, the residual blood and effusion was breathed into pleural cavity, and intrathoracic drain was then implanted. The chest wall muscles were sutured layer by layer, the subcutaneous tissue and skin were closed and the incision was cleaned again. After surgical operation, dogs were sent to intensive care unit (ICU), and the respirators were used for breath-

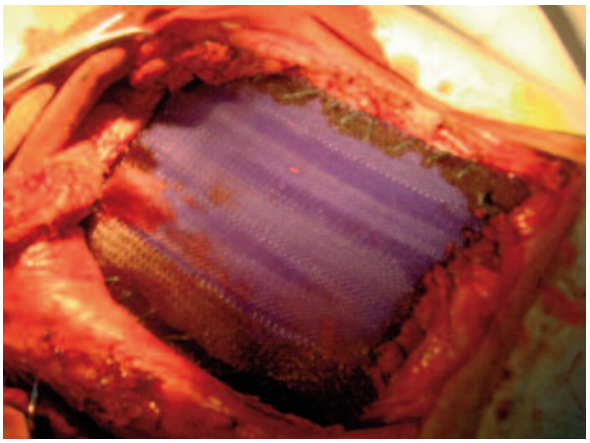

Figure 2. Application of PDO mesh in chest wall reconstruction in dogs.

ing. Blood and arterial blood gas were tested. The experimental dogs were caged separately after tracheal intubation extraction and recovery from anesthesia. For the three dogs as the control group, the same surgical procedure was performed and PP patch was utilized to repair chest wall defect.

The appetite, nose temperature, urine and skin incision of experimental dogs were investigated each day after operation. The thoracic drainage and color was observed, and the chest tube was pulled our generally after 24-48 hours after operation. Intramuscular injection of 2 mg/kg Butorphanol for analgesia and 20,000 U/kg procaine benzylpenicillin for infection prevention were implemented after the operation. A week after operation, ultrasonic inspection of pleural, blood routine and function of liver and kidney were reexamined. 1, 2, 6 month after operation, chest computed tomography (CT) examination was carried out for dogs. Dogs were intramuscular injected 10 mg/kg Ketamine for sedation before ultrasonic and chest CT examination. The animals were sacrificed by absorption of isoflurane and intravenous injection of sodium pentobarbital (200 mg/kg).

One experimental dog in the PDO group was sacrificed respectively at 30, 60 or 90 days after operation. Six dogs in PDO group and three in PP group were sacrificed at 180 days after operation. The thoracic wall undergone reconstruction was removed en bloc including the repaired part and the surrounding normal tissue. The specimens were fixed in 10% formalin, stained with hematoxylin and eosin, and histologically observed.

Evaluate the Correlation of Patch Adhesion

Adhesion between the patch and lung or diaphragm was found in pleural cavity in euthanasia dogs through thoracic exploration. According to the American Fertility Society classification standard, two surgeons evaluated and recorded the severity, type and range of adhesion, respectively (Table I).

Patch Shrinkage or Area of Chest Wall Bone Defect

After taking off the whole dog chest wall, two surgeons measured the gross area of bone defect, then judged and recorded independently. The mean value was taken as the observed result.

Statistical Analysis

All data were expressed as mean ±SD. Statistical significance ($p < 0.05$) was determined using the *t*-test and Fisher's exact test.

Results

After operation, the trachea cannulas were pulled out from all experimental dogs (PDO group and PP group) smoothly, and sent to the kennel to keep separately. Indwelling intrathoracic drain was removed within 24-48 hours after surgery. No abnormal breathing or respiratory failure in chest wall was observed in dogs after operation. Besides, no operational death occurred.

All animals' chest wall wound was healing physiologically, without chest wall hernia,

Table I. American Fertility Society classification

Adhesion characteristic	Scores
Extension of involvement	
< 25%	1
< 50%	2
< 75%	3
< 100%	4
Type	
Filmy, transparent, avascular	1
Opaque, translucent, avascular	2
Opaque, capillaries present	3
Opaque, larger vessels present	4
Tenacity	
Adhesion falls apart	1
Adhesions lysed with traction	2
Adhesion requiring sharp dissection	3
Possible total	11

hematoma or local infection. In PDO group, 1 dog accompanied with seroma, which was relieved by pressure dressing, and 1 dog with moderate effusion, which was relieved by thoracic drainage.

All experimental animals survived after operation during the follow-up period. No clinical infection or mesh related complications, i.e., shift, corrosion or fistula was observed. Through chest wall imaging, physical examination, autopsy and serial histologic examination, we found that on the one hand, PDO mesh stimulated the proliferation of fibrous tissue, on the other hand degraded gradually, and fused with chest wall tissue, eventually forming thick fiberboard (Figures 3, 4).

In PDO group, we found small or moderate degree of loose adhesion between PDO mesh and lung. The adhesion area was small, and the average scores were 1.5, 2, 3, 4.5, and 5.5 respectively (Figure 5). However, marked or moderate adhesion between patch and lung tissue was observed in PP group. In serious cases, covered by dense fiber tissue, the patch could be separated with sharp dissection, and the average adhesion scores were 5, 6.5 and 7.5 respectively. According to standard definition and scoring method of the American Fertility Society classification, mean adhesion score of PDO group was significantly lower than that of PP group (< 0.05, $p = 0.03$).

In post operation examination, we found that the areas of chest wall bone defect were decreased after application of the two kinds of patch materials. The average narrow areas of PDO group were 0.71, 0.61, 0.55, 0.65, 0.66 and 0.5 times of the control group (Figure 4). While the areas of PP group were 0.55, 0.38 and 0.42 times of the control group. Statistical analysis was significant (< 0.05, $p = 0.02$), showing that the contraction area of bone defect in PP group is more significant than that of PDO group.

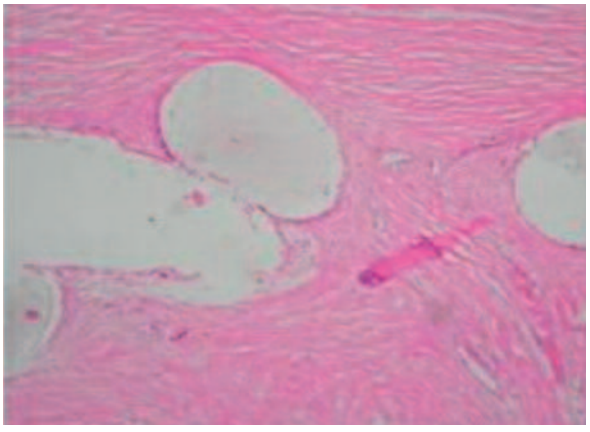

Figure 3. 30 days after operation, obvious fibrous tissue hyperplasia is observed around PDO monofilament fiber.

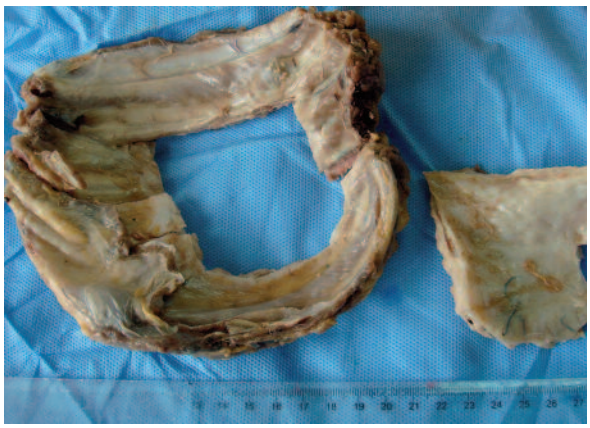

Figure 4. After formalin fixation, the chest wall around PDO repairing part resembled rectangle 7 cm×6.5 cm with obvious thickening fibrous layer.

Discussion

Our study shows the effectiveness of PDO mesh in the reconstruction of chest wall defect. The PDO mesh could remedy the chest wall defect, and no abnormal movement of chest wall, incision infection or poor tissue healing are observed post operation. More importantly, after growing into the surrounding tissue, the PDO mesh is degraded gradually, forming a compacted fiber layer, which is demonstrated by clinical

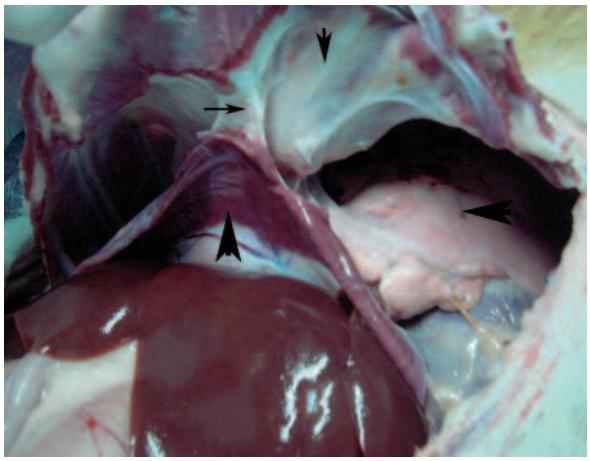

Figure 5. The lateral chest wall was examined in euthanasia dogs. Right arrow represents diaphragma, left arrow represents lung, lower arrow represents the repaired chest wall, slope arrow represent adhesions between the chest wall and lung or diaphragma. In this case, the adhesion score is 3.

observation, imaging and histologic examination. Moreover, the PDO mesh leads to smaller shrinkage of bone defect area, and a milder extent of lung adhesion compared with the PP patch.

Reconstruction of chest wall with PDO mesh induces minor complications which require no treatment or simple treatment. For example, due to anatomical dead space, incision seroma occurs in one case, which is relieved by pressure banding. Moderate amount of pleural effusion occurs in another case, which is improved after thoracentesis. It is caused by the stimulation of the patch exerts on the visceral pleura. Alternatively, it is induced by the permeation of the defected tissue exudate into the pleural cavity through the patch mesh. Therefore, the application of PDO in surgery is feasible and safe.

Mechanical Property of PDO

Chest wall is a dynamic structure. The patch sustains the stretching caused by the movement of the chest wall muscles and ribs, and endures the changes of pleural cavity pressure. During tissue healing process, the metabolites affect the patch. In addition, the patch might be corroded by inflammation of the pleural cavity and lung. Therefore, higher requirements are placed on the physical and mechanical properties of the surgical patch for chest wall reconstruction.

LeRoux and Shama[12] believed that except for intrinsic inertness, plasticity and radiation permeability, the ideal synthetic material for reconstruction should first possess a certain mechanical strength to eliminate the abnormal movement of the chest wall. At present, there is a lack of evaluation criterion for the synthetic material, which is used for chest wall reconstruction in clinical practice. Fortunately, the synthetic material, that meets the standard of hernia surgery and abdominal wall reconstruction, usually can be safely applied to the chest wall reconstruction[8,13]. For example, the mechanical behavior of commonly used PP and ePTFE can provide sufficient tensile strength required for chest wall reconstruction.

In general, the surgery patch and the fixed sutures provide semihard or hard mechanical support to stabilize chest wall in weeks after the reconstruction surgery. In the healing process, dense fibrous capsule or prosthesis-fibrous capsule complex are formed in exogenous reaction in 4-6 weeks, acting as appropriate and reliable chest wall layer and providing sufficient supporting force[6]. Study shows that PDO possesses strong strength and modulus, and slow biodegradation rate. It maintains 70% of initial strength in 3 weeks, 40% in 6 weeks, 15% in 2 months in vivo. The PDO can be absorbed completely in 6 months[14]. Therefore, the mechanical properties of the PDO material determine its application in chest wall reconstruction.

The PDO mesh we prepared has sufficient tensile strength and burst strength to stand the tension of the chest wall. Meanwhile, the mesh facilitates the infiltration and absorption of the tissue exudate into the pleural cavity. This also explains the occurrence of seroma in the chest wall. Our study demonstrates that, the PDO mesh can be separated from the tissues with a favorable shape in a month after operation, but hard to be separated with obvious profile in two months. However, the PDO mesh is fused with the chest wall without intact shape in three months after the surgery. This is different from the general understanding of PDO material. In previous view, PDO material could be degraded and absorbed basically according to property study of suture or monofilament fiber. Actually, the half-life of suture is markedly distinct in different tissue environment[15].

Degradable tracheal stent, esophageal stent and intravascular stent can be developed with PDO material. Limited conclusions from incomplete observations prove that the degradation and absorption time of different parts of stents is distinct[16-17]. For example, the tracheal stent disappears in 5-10 weeks, and no signs of any residual polydioxanone fibers is observed in 15 weeks. Esophageal stent fragments in 3 months, and dissolves in 6 months. While intravascular stent is partially absorbed in 90 days. Zilberman et al[7] considered that the degradation of PDO stent was dependent on the diameter of fiber, structure of prosthesis and the histological type of the environment. The microorganism, inflammation and low pH value might accelerate the degradation speed of PDO and the loss of initial tension[18]. It is easy to understand that the degradation speed of PDO in tracheal stent and esophageal stent based on above reasons.

The healing process is completely different when utilizing sutures PDO or PDS. Although the degradation speed of PDO monofilament is stable, the degradation and metabolism of PDO products is distinct due to different spatial structures and tissue environment. We believe that, the degradation and absorption capacity of the chest wall tissue contacting with PDO mesh is different and limited, which may be affected by peripheral blood supply and metabolites. Besides, the weaving structure of the PDO mesh itself produces load and difficulty to the degradation,

thus slowing down the absorption speed. Therefore, we believe that, the maintenance of mechanical support of PDO mesh in chest wall reconstruction may be longer than we expected before. However, it remains to be investigated by biomechanics of the chest wall tissue.

Judgement of Lung Adhesion

Any form of trauma will cause fibrin exudation, and form adhesion. Adhesion is formed easier if accompanied by ischemia, inflammation or exogenous (for example, meshes). In these situations, they mature into tissue adhesions. Lung adhesion is the most common complication in chest wall reconstruction, which hinders the lung expansion significantly, thus affecting the pulmonary function. For instance, the microporous structure of expanded polytetrafluoroethylene (ePTFE) prevents the pervading growth of the tissue, thus avoiding adhesion while increasing infection. However, the porous structure of PP leads to serious lung adhesion [6]. Therefore, researchers design composite mesh, PP/ePTFE mix and hybrid mesh with an absorbable surface. For example, Parietex (Covidien) provides an additional surface to block the adhesion between the visceral and the patch. However, experiments show that, although it inhibits adhesion in short time, it is helpless after a month. The key point is that there is no definite time dynamics for the adhesion[19].

There is no corresponding objective standard to estimate the relative patch adhesion in chest wall reconstruction. The standard of hernia patch adhesion can be referred to evaluate the chest wall reconstruction[20]. Compared with the PP group, no or mild adhesion is observed in PDO group, and the adhesion decreases significantly. The study indicates that PDO induces milder adhesion in a smaller area and affects lung slightly. A reasonable explanation is that PDO material is degradable, which produces milder exogenous reaction and inflammation, thus affecting the organism slightly and reducing the adhesion. The adhesion is associated with the property of the patch material, as well as the patch structure, pore size, contact area and application environment. Obviously, our study comprehensively presents the effect of the PDO mesh lung adhesion. The advantage of PDO mesh is revealed when comparing the aperture and fiber structure in a more strict observation. However, the existing research is enough to illustrate the advantage of PDO mesh which leads to less lung adhesion and reduces interference on pulmonary function.

Shrinkage of PDO Mesh and Change in Areas of Bony Defect

Mesh shrinkage is induced by the contraction of granulation tissues or scar tissues around the mesh. Shrinkage of implanted mesh is a potential problem in the hernia and abdominal wall defects, because it will cause hernia relapse and postoperative pain[21]. Relevant study found that the shrinkage of PP, PTFE, Vypro II mesh was 75%, 45% and 29% respectively, which could reduce wound contraction to 60% of original area[22]. Mesh shrinkage actually reflects the contraction of wound areas, which is required for body repairing, while injures the organism at same time. Few studies have mentioned the shrinkage of implanted mesh and change in areas of bony defect after chest wall reconstruction, while these changes may induce chest wall discomfort, pain, and even appearance and movement.

PDO mesh cannot be seen in x-ray, so the change of bony defect areas is measured to speculate the patch correlation. Our results show that the defect areas of PDO group and PP group are all reduced, but that of PP group is more obvious. As exogenous substance, PDO and PP patch stimulate the body to produce a foreign body reaction, including inflammation, fibrogenesis, calcification, thrombus and granulomatosis. The contraction of granulomatosis and scar tissue around patch induces the shrinkage of patch, driving the contraction of wound areas. Although hydrolyzed, the PP material is stable. It constantly stimulates the body to produce fiber reaction and form fibrous capsule-prosthesis composite structure, thus repairing and fixing chest wall with a high shrinkage. PDO material is characterized with good biocompatibility, mild foreign body reaction, and biodegradable, which forms few fiber granuloma, mild shrinkage in the formation of natural scar tissue, and small change of area. And the similar symptoms have been observed in abdominal wall reconstruction, like mild inflammation and fibrotic tissue reaction, smaller granuloma, less cell turnover and remodeling[23]. It is consistent with the result that shrinkage of the PDO material is low in chest wall reconstruction.

From anatomic point of view, the contraction of the chest wall defect area or patch area often means the change in thoracic shape. It is natural that, less contraction barely affects the thoracic shape, and exerts a small effect on the compliance and movement of the chest wall. We speculate that in the chest wall reconstruction, PDO mesh have a small impact on the body, which is conducive to the rehabilitation. Some Authors advocated that absorbable patch may reduce postoperative chronic pain and paresthesia[24].

It is still unknown whether PDO has the same effect due to the limit of animal experiment. Certain material-related infection rate exists in chest wall reconstruction, which is attributed to the risk of chronic infection and the possibility rejection. The research does not have sufficient evidences to explain the associated infection of PDO material.

Our study shows that PDO mesh can close down the function of chest wall defect, and PDO patch can be degraded gradually and forms a fibrous layer with the surrounding tissues. Besides, PDO mesh leads to slight lung adhesion with a small shrinkage. These results are confined to our observation, and a favorable biodegradable material may have better results. Further study is needed to prove the result.

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