Original Article

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Evaluation of electrospun composite biomaterial and porcine small intestine submucosa patch in open inguinal herniorrhaphy: A prospective, randomized, single-blind, controlled, multicenter, 72-month clinical study

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SUMMARY: The aim of this study was to compare postoperative complications and long-term clinical efficacy of electrospun composite biomaterial and porcine small intestine submucosa (SIS) patch in open inguinal herniorrhaphy. A prospective, randomized, single-blind, controlled, multicenter study was used to select 172 patients with inguinal hernia who met the inclusion criteria in 3 hospitals. All participants were randomly assigned (1:1) and treated by open inguinal herniorrhaphy. The experimental group used electrospun composite biomaterial patch and the control group used SIS patch. Complications were assessed by ultrasonic volume auto-scan (UVAS) at 6, 33 and 72 months after operation. The results showed that 53 cases were found to be positive by UVAS, including 20 cases of encapsulated effusion (12.74%), 11 cases of soft tissue edema (6.40%), 4 cases of recurrence (3.01%), 2 cases of testicular ischemic atrophy (1.50%), 7 cases of testicular hydrocele (5.26%), 6 cases of varicocele (4.51%), 2 cases of spermatic cord cyst (1.27%) and 1 case of epididymal head cyst (0.64%). At 33-month follow-up, 2 cases recurred in the control group (2/79, 2.53%) while none in the experimental group (0/78) (the 95% CI difference in effective rates between the two groups was -0.93% to 6.00%, within the preset non-degradation range of Δ10%). At 72-month follow-up, there were 4 cases of recurrence in the control group (4/59, 6.78%), while none in the experimental group (0/60) (the lower limit of 95% CI difference in effective rates between the two groups was 0.27% > 0). The main clinical efficacy of the experimental group was better than that of the control group. There was no statistical difference in the secondary efficacy between the two groups. The postoperative safety evaluation effect of the two groups was the same. Long-term follow-up with UVAS after operation showed that the main clinical efficacy of electrospun composite biomaterial applied in this procedure was superior to that of SIS patch, and there was no significant difference in the secondary efficacy between the two biological patches.

Keywords: biological patch, tension-free inguinal herniorrhaphy, postoperative complications, ultrasonic volume auto-scan

1. Introduction

Inguinal hernia is a common surgical disease, and surgical treatment is the preferred method for treating inguinal hernia. In the past 30 years, the tension-free repair technology using repair patches has become very mature and has basically replaced traditional tissue suturing techniques. Traditional patch is usually made of polypropylene. Although it has been widely used in clinic, the incidence of postoperative chronic pain is as high as 10%~12% due to its non-absorbable characteristics (*1-3*), and more than 25% of patients' daily activities and weight-bearing functions are restricted, which affects their quality of life (*4-6*).

In recent years, the material science has developed rapidly. Biological repair materials such as porcine small

intestinal submucosa (SIS) patch, electrospun composite biomaterial and porcine basement membrane patch have been accepted by surgeons and are gradually used in inguinal and incisional herniorrhaphy. Compared with traditional synthetic patches, biological patches have significant advantages such as good biocompatibility, no excess scar tissue, no long-term chronic inflammation, and light tissue adhesion, which can effectively reduce the risk of long-term complications after adult open inguinal herniorrhaphy (*7-8*). Its degradability effectively increases the compliance of the abdominal wall and the postoperative comfort of patients, which can significantly improve the quality of patients' postoperative life and protect their fertility (*9*). Of course, the use of biological patches in herniorrhaphy may also result in postoperative complications such as encapsulated fluid accumulation or recurrence. The current guidelines for the treatment of adult inguinal hernia do not provide detailed recommendations for the comparison and selection of different types of biological patches.

This study compared the use of two different biomaterials in adult inguinal hernia repair surgery, diagnosed postoperative complications through ultrasonic volume auto-scan (UVAS), and explored the mid to long term clinical efficacy of using biomaterials in open tension-free inguinal herniorrhaphy.

2. Methods

2.1. Ethical statement

This study was approved by the Clinical Research Ethics Committee of the local hospital and was retrospectively registered in 2017 (ChiCTRINR-17010723).

2.2. Participants

From July 2014 to March 2015, patients with unilateral inguinal hernia were recruited from Huadong Hospital, Shanghai Tenth People's Hospital and Shanghai Putuo Hospital. All subjects in the study, who were Han adult man, participated voluntarily and signed informed consent forms.

The subjects aged 18-79 years who had a unilateral primary inguinal hernia with American Society of Anesthesiology grade I-III, were eligible for this study. According to the Chinese classification of groin hernia recommended by the Committee of Hernia and Abdominal Wall Surgeons of the Chinese College of Surgeons, inguinal hernia can be divided into type I-III. Exclusion criteria were: bilateral hernia, recurrent hernia or incarcerated hernia; patients who were allergic to anti-adhesive film; patients with contraindications to surgery, such as serious cardiopulmonary disease, coagulation dysfunction, and abnormal liver and kidney function; patients with previous reproductive dysfunction or undergoing genitourinary surgery that may affect reproductive function; patients with malignant tumors whose life expectancy were less than 6 months; patients with mental and neurological illness who were noncompliant with their doctors.

2.3. Study design and procedures

According to one published study, the recurrence rate of SIS patch was 4.9% (*10*). So, 5% was used as the established recurrence rate in this study. The sample size was based on the main clinical efficacy measure (recurrence rate) and the non-inferiority evaluation formula: $n = [(Z1-\alpha/2+Z1-\beta)/(PT-PC-\delta)]2\times[PT(1-PT)+PC(1-PC)]$, $\alpha = 0.025$, $\beta = 0.10$, non-inferiority threshold $\delta = 10\%$, the required number of cases in each group was 75. Assuming that the exclusion rate was 10% and the recurrence rate of the experimental group was similar to that of the control group, the sample size was 86 cases in each group, a total of 172 cases.

In this randomized, single blind, controlled, multi-center study, 172 subjects selected from three hospitals were randomly assigned to the experimental group and control group according to a ratio of 1:1. The experimental group was treated with electrospun composite biomaterial patch (P[LLA-CL]/fibrinogen patch; Shanghai Pine&Power Biotech Co., Ltd., China), while the control group was treated with SIS patch (Biodesign Surgisis; Cook Biotech Inc., USA). Both groups used a custom-made patch of the same size (6 × 14cm). The surgical method of open tension-free inguinal herniorrhaphy was technique of abdominal wall reinforcement with biological mesh (*11*). All participating surgeons were invited to participate in a specific training course organized by the Training Center of Huadong Hospital of Fudan University to ensure that they used the same standard techniques in this study. Only the surgeon performing the operation was aware of the assignment. Patients, investigators, and other researchers were blind to the allocation information throughout the entire study.

Siemens Acuson S3000 UVAS, with probe model 14L5BV and 1 mm scan spacing, was used to examine the surgical incision, chronic pain site and scrotum of the patient at 6, 33 and 72 months postoperative. A single scan captured ultrasonic volume images of a 15.4 cm (length) × 16.8 cm (width) × 6.0 cm (depth) area. Positive ultrasound diagnoses after operation, all of whom were confirmed by puncture, surgery or other imaging examinations, included encapsulated effusion, soft tissue edema, recurrent hernia, hydrocele of testis, atrophy of testis, varicocele, *etc*. Negative ultrasound diagnostic criteria after surgery were: good peritoneal continuity in the repair area, flat patch, no hydrops in the preperitoneal space, free movement of spermatic cord at the reconstructed inner ring and no abnormal echo in the ipsilateral spermatic cord and scrotum.

Simple verbal scale (SVS) and visual analogue scale (VAS) questionnaires were administered to assess

patients' pain at rest and cough at each follow-up period. SVS included 5 grades: none, mild, moderate, severe and intolerable. VAS used a 100 mm straight line without numbers, scales or words. The left end of the line (0 mm) represented no pain. The right end (100 mm) represented maximum pain. The middle part indicated different levels of pain. Let the patient make a mark on the horizontal line to indicate the level of pain.

Activities of daily living (ADL) questionnaire was used to assess the patients' quality of life at each follow-up period (*12*). ADL was scored by the Barthel index (*13*) during daily work, strolling, jogging, sexual life and weight-bearing exercise. There were four level of 100 points. Level 0: ability intact, 100 points. Level 1: mild dependence, 61-99 points. Level 2: moderate dependence, 45-60 points. Level 3: heavy dependence, ≤ 40 points.

2.4. Curative effect evaluation

The primary clinical efficacy was determined by effective rate and recurrence rate at 6, 33 and 72 months after surgery. Effective rate = 1 - recurrence rate. Recurrence rate = Recurrence cases/total study cases × 100%. The secondary efficacy at each follow-up period was evaluated based on other positive ultrasound diagnoses, SVS and VAS scores and ADL scores. The postoperative safety was judged according to serious complications such as incision infection, patch infection and bladder injury.

2.5. Statistical analysis

PASS 22.0 was used for statistical analysis. Count data were described by composition ratio. The independent *t*-test was used for inter group comparison of normally distributed measurement data, and Wilcoxon rank sum test was used to compare numerical data with a non-normally distributed. The non-inferiority test and superiority test of two groups were conducted for the main evaluation indexes, and the non-inferiority margin was -10%. The comparison between enumeration data was conducted by the chi square test or Fisher's exact test.

3. Results

3.1. Comparison of the basic characteristics of the two groups

One hundred and seventy-two patients with inguinal hernia who met the inclusion criteria were selected in this study. There were 86 cases in the experimental group and the control group. No cases were lost at the 6-month follow-up after surgery. The total number of patients was 157 at the 33-month follow-up, including 8 cases lost in the experimental group and 7 cases lost in the control group. At the 72nd month, 133 people completed follow-up, including 12 cases lost in both the experimental group and the control group. Among these lost cases, 5 cases withdrew consents due to patients' own choices, 22 cases had insufficient data or missing examinations, 2 cases had colon mass lesions, 1 case had pancreatitis, 1 case had fever, 1 case had myocarditis, and 1 case had lung mass lesions. 6 cases were lost for unknown reasons. There was no statistical significance in the comparison of basic characteristic data between the two groups ($P > 0.05$, Table 1).

3.2. Postoperative complications diagnosed by UVAS

During 72 months after operation, 53 positive ultrasound diagnoses were found, including 4 cases (3.01%) of recurrent hernia, 20 cases (12.74%) of encapsulated

Table 1. Comparison of basic characteristics of 172 enrolled patients

Variable		Experimental group (n = 86)	Control group (n = 86)	P
Cases in each center	Huadong Hospital	40	40	> 0.05
	Shanghai Putuo Hospital	11	13	> 0.05
	Shanghai Tenth People's Hospital	15	13	> 0.05
Age (years)		58.15 ± 12.61	57.20 ± 13.44	> 0.05
gender	male	86 (100.00%)	86 (100.00%)	> 0.05
Height (cm)		170.87 ± 5.44	171.61 ± 6.04	> 0.05
Weight (kg)		68.25 ± 9.70	68.25 ± 9.03	> 0.05
BMI (kg/m^2)		23.33 ± 2.78	23.15 ± 2.61	> 0.05
Marital status	Be married	78 (90.69%)	79 (91.86%)	> 0.05
	Unmarried	8 (9.30%)	7 (8.13%)	> 0.05
Job	Physical work	23 (26.74%)	26 (30.23%)	> 0.05
	Non-physical work	63 (73.25%)	60 (69.76%)	> 0.05
Inguinal hernia classification (case/%)	Type I	26 (30.23)	23 (26.74)	> 0.05
	Type II	53 (61.63)	57 (66.28)	> 0.05
	Type III	7 (8.23)	6 (6.98)	> 0.05
Preoperative ASA grade assessment (case/%)	Grade I	45 (52.33)	46 (53.49)	> 0.05
	Grade II	40 (46.51)	39 (45.35)	> 0.05
	Grade III	1 (1.16)	1 (1.16)	> 0.05

effusion in the surgical area (Figure 1), 11 cases (6.40%) of soft tissue edema, 2 cases (1.50%) of ischemic shrinkage in testis (Figure 2), 7 cases (5.26%) of hydrocele, 6 cases (4.51%) of varicocele, 2 cases (1.27%) of spermatic cyst and 1 case (0.64%) of epididymal head cyst. There was no significant difference in positive ultrasound diagnosis between the two groups in each follow-up period ($P > 0.05$).

3.3. Analysis of the primary clinical efficacy of the two groups

According to the Clopper-Pearson method, the lower limit of the 95% confidence interval (CI) for the difference of effective rate between the two groups was -0.93% at 33 months and 0.27% at 72 months after surgery. When the lower limit of the difference was greater than the pre-set non-inferior cut-off value (-10%), the invalid hypothesis was rejected. Therefore, the efficacy of the experimental group at both 33 and 72 months after inguinal herniorrhaphy was not worse than that of the control group. Based on the superiority test, when the lower limit of the 95% CI for the efficiency difference between the two groups, which was 0.27% at 72 months after surgery, was greater than 0, the effective

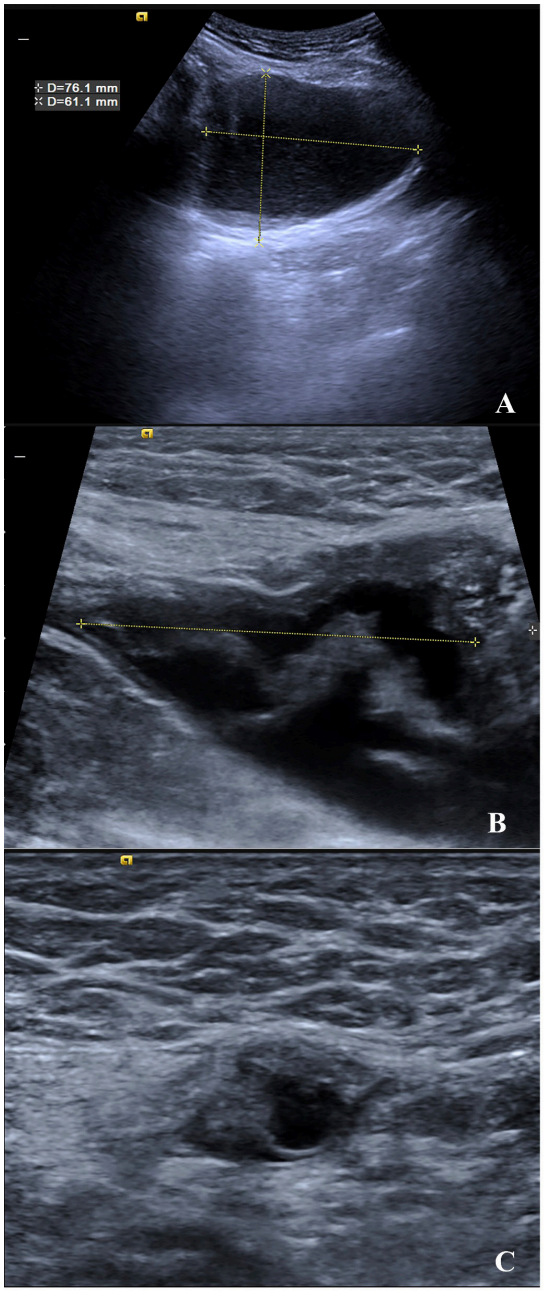

Figure 1. The encapsulated effusion caused by the degradation of the biological patch in the same patient at 6 (part A), 18(part B), and 33(part C) months after surgery.

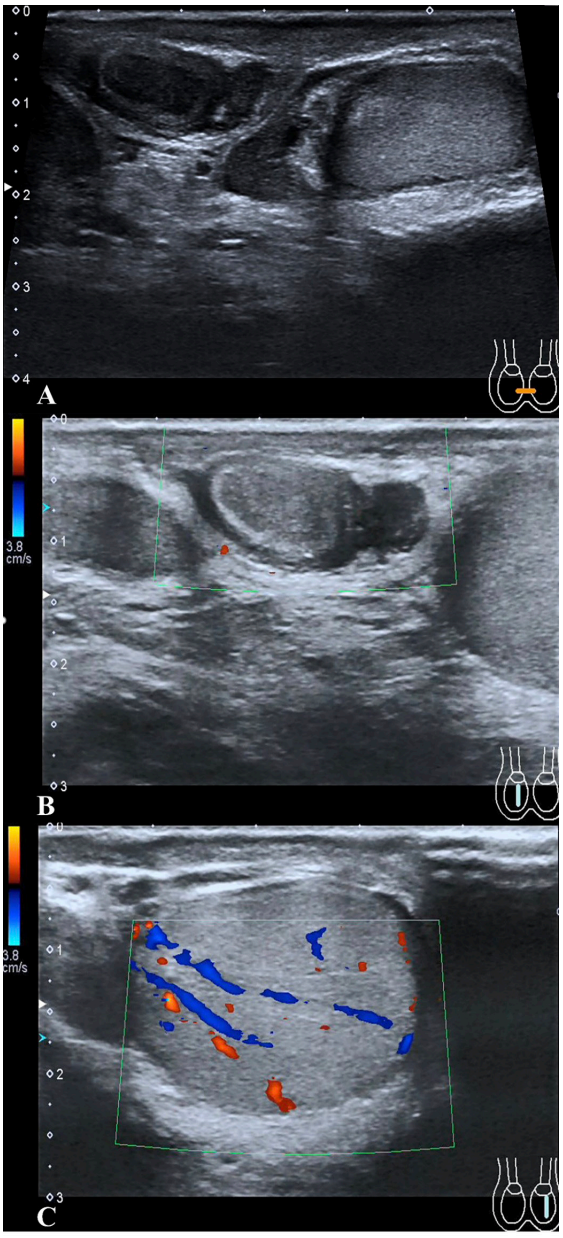

Figure 2. The comparison between the right testicular ischemic shrinkage and the left normal testis. Part A: the comparative image of testes on both sides. Part B: no color blood flow signal in the right reduced testis. Part C: color blood flow signal in the left normal testis.

rate of the experimental group was better than that of the control group. Therefore, the efficacy of the experimental group at 72 months after inguinal herniorrhaphy was better than that of the control group (Table 2).

3.4. Comparison of the secondary efficacy and the postoperative safety

When the patients' postoperative pain was assessed by SVS and VAS scores, there was no statistical significance in the evaluation of SVS and VAS of resting state and coughing between the two groups during each follow-up period ($P > 0.05$).

We used ADL scores to evaluate the patients' postoperative quality of life, and found that there was no statistical significance between the two groups in the scores of daily work, walking, jogging, riding, sexual life and weight-bearing exercise during each follow-up period ($P > 0.05$). Among all patients, there were significant differences in the ability impairment in jogging, sexual life and weight-bearing exercise compared to that of walking in each follow-up period ($P < 0.05$). The incidence of moderate and severe ability impairment in jogging, sexual life and weight-bearing exercise is higher than that in walking, as shown in Table 3.

No other complications such as patch or incision infection or bladder injury occurred in both two groups, so the safety evaluation effect of the two groups was equal.

4. Discussion

The rapid development of materials science has further promoted the research and development of new biological patches and their application in inguinal herniorrhaphy. The clinical application of acellular matrix biological patch was early. Currently, available acellular matrix biological materials include human dermis, porcine small intestinal submucosa, porcine dermis, and fetal bovine pericardium, *etc.* (*14*). It takes homologous or xenogenic skin, intestinal submucosal tissue and other collagen matrix as materials, and uses special methods to retain the collagen fiber network structure of the extracellular matrix as the skeleton, stimulates and induces the patient's own fibroblasts or

Table 2. Non-inferiority test and superior test of postoperative effective rate of two groups

	33 months follow-up			72months follow-up		
	Experimental group	Control group	Efficiency difference	Experimental group	Control group	Efficiency difference
Case, *n*	78	79		78	79	
Recurrence, *n*	0	2		0	2	
effective rate (%)	100	97.47	2.53	100	97.47	2.53
95% CI	95.38-100	91.15-99.69	-0.93-6.00	95.38-100	91.15-99.69	-0.93-6.00

Table 3. Comparison of postoperative activities of daily living of all patients in each follow-up period

	ADL grade				No such activity	Chi-square test	*P*
	0	1	2	3			
6 months follow-up, *n*							
Walking	162	10	0	0	0		
Daily work	147	11	2	0	12	2.345	0.3096
Riding	149	9	4	2	8	6.409	0.0933
Jogging	137	15	5	2	13	9.595	0.0223
Sexual life	135	9	5	6	17	12.658	0.0054
Weight-bearing exercise	131	13	13	8	7	24.536	< 0.0001
33 months follow-up, *n*							
Walking	150	7	0	0	0		
Daily work	137	8	0	1	11	1.378	0.4999
Riding	141	9	1	1	5	2.657	0.4476
Jogging	128	11	4	3	11	9.828	0.0201
Sexual life	130	6	2	5	14	8.219	0.0417
Weight-bearing exercise	125	8	13	6	5	22.274	0.0001
72 months follow-up, *n*							
Walking	127	6	0	0	0		
Daily work	117	6	0	1	9	1.096	0.5781
Riding	120	8	1	1	3	2.45	0.4844
Jogging	106	10	4	3	10	9.517	0.0232
Sexual life	111	4	3	4	11	8.016	0.0457
Weight-bearing exercise	101	10	10	7	5	20.877	0.0001

collagen to use this skeleton for adhesion and migration (*15*), and constantly repairs and strengthens itself, thus achieving the purpose of repairing peritoneal defects (*16*). At the same time, the material itself can be degraded in the body (*17*).

In recent years, an electrospun composite biomaterial has shown unique advantages in the field of hernia treatment. It is made of fibrinogen and absorbable polymer, using nano electrostatic spinning technology. The material has excellent superhydrophilicity and histocompatibility, which is conducive to the recruitment and adhesion of wound healing factors and regenerated cells. Its stable three-dimensional mesh scaffold structure and large specific surface area can make the new tissue grow in and reshape regeneration while the material degrades. The metabolites are non-toxic, non-allergenic and can be completely degraded and absorbed (*18-19*).

Of course, the biological patch also has some defects. In the ideal state, there is a dynamic balance between biological patch degradation and tissue remodeling. But in fact, when the patch degrades too early, the extracellular matrix cannot maintain local tension in time, which can easily lead to local swelling or even recurrence after surgery (*20*). Some researches found that there were certain similarities in the changes of mechanical properties and degradation processes between electrospun composite biomaterials and SIS patches. After being implanted into dogs, the burst strength of SIS patch and PLCL/Fg patch rapidly decreased within the first two weeks. Subsequently, the biological scaffold gradually remodelled and recovered its strength, maintaining it for at least two years (*21-22*). This early decline in strength load was related to the rapid degradation of the biological scaffold, cell infiltration, and deposition of new host matrix (*23*). Meanwhile, the strength of the host abdominal wall itself also played a very important role in success or recurrence of the early time in repair (*24*). Some studies found that the postoperative recurrence rate of using SIS patch was 4.9% (*25,26*). In our study, the recurrence rate of electrospun composite biomaterial was 0%. However, the compliance of the subjects decreased during the long 6-year period, and the follow-up loss rate of the experimental group was 23.2%. Therefore, it cannot be ruled out that there may be a bias in the lower recurrence rate of the research data. The cross-linking structure greatly increases the mechanical strength of the acellular matrix biological patch. However, if the cross-linking is excessive, chronic inflammatory stimulation will be formed in the long-term degradation process of this collagen fiber network structure, and the proliferation of fiber tissue will far exceed the remodeling of biological scaffold tissue, which ultimately causes postoperative foreign body sensation or chronic pain (*27-29*). Other studies reported that the incidence of chronic pain after biological patch surgery exceeded 4.0% (*30*). In this study, the chronic pain and long-term quality of patients' life using biological patch were preliminarily explored. Chronic pain still affected a small number of patients' jogging, sexual life and weight-bearing exercise after operation. The hyperacute rejection caused by the active surface area of biological patch is an important reason for the seroma after implantation of biological patch (*31*). Some researches showed that the incidence of the seroma after implantation of biological patch was higher than that of synthetic patch (*32-33*). In our study, a patient who used electrospun composite biomaterial patch developed encapsulated hydrops after operation. During the follow-up period, he underwent five punctures, all of which the transparent light-yellow jelly-like substances were extracted. Finally, the hydrops disappeared completely 36 months after operation. For obese patients, the wound is prone to fat liquefaction, and the incidence of hydrops after using biological patches is also high. Therefore, wound healing will be affected and even patch infection may occur (*34*).

The diagnosis rate of various complications after inguinal herniorrhaphy by ultrasonography is as high as 90% (*35*). Ultrasound can display the full anatomical picture from the skin to the abdominal wall, clearly observe the conditions of the patch, peritoneum, and surgical area (*36*), and easily diagnose common postoperative complications such as recurrence and fluid accumulation. Meanwhile, ultrasound can also accurately observe the subtle morphological and structural changes such as patch folds, spermatic cord slippage and intestinal adhesion, which can help patients avoid reoperation to find the cause of postoperative chronic pain (*37*). In addition, ultrasonography, due to its advantages of fast operation, good repeatability, no radiation and flexible change of examination position, has a higher diagnostic efficiency than other imaging examinations (such as CT and MRI) for obese patients and recurrent hernias with thick hernia sac wall or small hernia sac (*38*). UVAS plays a complementary role to traditional ultrasound by adding coronal image display on the basis of two-dimensional ultrasound image, providing surgeons with the intuitive surgical visual plane (*39*). Therefore, using ultrasound and UVAS together has important application value in the diagnosis of various postoperative complications of inguinal hernia repair.

5. Conclusion

In conclusion, the long-term follow-up of open tension-free inguinal herniorrhaphy with biological patches through UVAS showed that the long-term clinical efficacy of electrospun composite biomaterials applied in this operation was superior to that of SIS patches. There was no significant difference between these two biological patches in chronic pain after surgery and the quality of patient's postoperative life. The postoperative safety of both was equal.

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