

## Original Article

# Treatment for displacement of PAAG mixture after injection augmentation mammoplasty

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**Abstract:** Background: The incidence of serious complications after augmentation mammoplasty with injection of polyacrylamide hydrogel (PAAG) was high. Objective: To design a new method for healing of the cavities and cysts after augmentation mammoplasty. Methods: 102 patients in whom PAAG exceeded the breast and spread to the thoracic-abdominal walls were enrolled and divided into two groups. Results: The flowing masses of different sizes exceeded the breast and spread to the thoracic-abdominal walls, and a large number of PAAG showed flowing degenerative mixture in the tissues and were invaded by many inflammatory cells. PAAG deposited extensively in the breast tissues, armpits and space of the thoracic-abdominal wall, and the breast was connected with the abdominal wall through the fistula of different sizes. At 2 weeks, the percentages of decrease in drainage volume and in lesion lacuna size of the thoracic-abdominal wall (82% and 80%, respectively) in patients receiving the multiple incisions combined with radical therapy were significantly different from those who did not receive the multiple incisions (46% and 45%) (Both  $P < 0.01$ ). At 4 weeks, in some of the patients receiving the multiple incisions combined with radical therapy, the lacuna of the thoracic-abdominal wall disappeared completely, and the lesions with flowing masses had been cleared. Conclusions: The new method of subareolar incision combined with surgery for inferior segment of mass to clean the mixture and thoroughly eliminate the lacuna of the thoracic-abdominal wall as well as suture to close the intramammary fistula can improve the treatment efficacy.

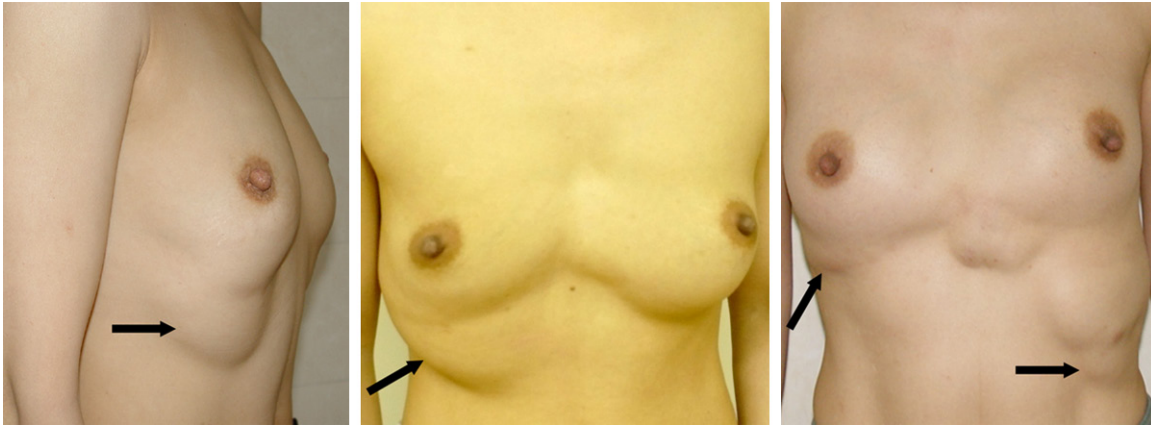
**Keywords:** Polyacrylamide hydrogel, augmentation mammoplasty, complication, malposition, chronic fistula

## Introduction

We have explored the new surgical methods and ideal biomaterials to improve the shape and structure of deformed breast in women [1-3]. Polyacrylamide hydrogel PAAG (Trade name: Interfall) produced by Ukraine was used to fill the face, breast and limbs for the first time in the world in 1987 [3], and was applied clinically in more than 30 countries of Europe, Canada, USA, New Zealand, Australia, South America and Asia subsequently [4, 5]. Since 1996, more than 200,000 women have adopted commonly used PAAG in clinic as the filling material for augmentation mammoplasty in China.

Since PAAG injection for augmentation mammoplasty is used, numerous women undergo terrible consequences in China [4, 5]. Especially in the past ten years, all the cases of PAAG

injection for augmentation mammoplasty exhibit varying degrees of local reactions and toxic/side effects, which also cause serious adverse reactions. Moreover, it is unlikely that all the PAAG materials can be cleaned, and the secondary complications emerge in endlessly [6-8]. At present, among the complications due to PAAG injection for augmentation mammoplasty, displacement of PAAG mixture is more common and raises concern. The injectant forms the subcutaneous masses that can move with the position, and even exhibits distant displacement (e.g., displacement to axilla, forearms and the thoracic-abdominal wall). Improper operation during treating early complications would cause damage, bleeding and infection of the new tissues. Saline is injected into the induration under a pressure to make the capsule rupture, massaging and squeezing to result in PAAG diffusion of the induration. The inappropriate treatment may cause the severe



**Figure 1.** Failure in controlling the local symptoms of PAAG displacement and recurrent cyst and mass in the thoracic-abdominal wall after augmentation mammoplasty.

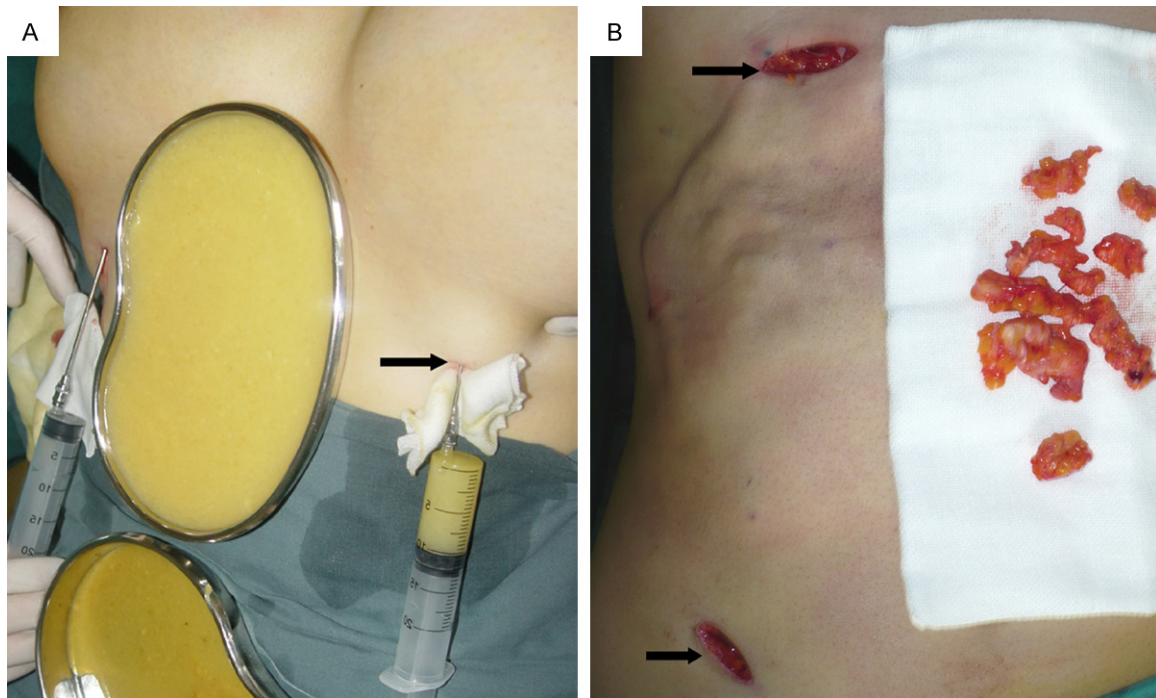
consequences of septicopyemia or mastectomy [9-12].

Currently, the aspiration method used for treatment in clinic is difficult to completely remove PAAG, and easily leads to hydrogel diffusion and side injury of the breast under the blindness [13]. Especially for the sac and induration formed after multi-level, scattered and multi-point injection, it is difficult to remove the filling materials, and the re-injury of the tissues due to repeated aspirations and punctures-induced injectant displacement cannot also be ignored [14].

PAAG displacement in patients receiving PAAG injection for augmentation manifests as loss of the symmetry of the shape and contour, PAAG exceeding the retromammary cellular space and displacing outside the design site to form subcutaneous or mobile masses with the position, or hydrogel-formed capsule rupture due to the subsequent violent extrusion to cause hydrogel displacement [9]. The mobility of hydrogel along intermuscular gap has been confirmed in animal experiments [15]. In the last decade, the patient's condition is more complex, which is reflected by expanding scope of PAAG displacement, diverse levels of infiltrated organizations and severe pathological changes of cells and tissues. Furthermore, a large number of patients suffered from intramammary fistula to induce extensive flowing deposition of the mixture of PAAG and necrotic and degenerative tissues in the thoracic-abdominal wall and form massive cavities and cysts in the thoracic-abdominal wall. For such patients, incom-

plete closure of the fistula and only removal of PAAG may clean the flowing deposition for the time being, but is difficult to completely treat the massive cavities and cysts in the thoracic-abdominal wall. The unhealed intramammary fistula, lesion tissue migration and infection of cavity in the thoracic-abdominal wall may appear after a certain time, thereby causing degeneration and necrosis of some tissues to damage the normal tissue structures [1, 16]. Therefore, it is necessary to explore a new surgical method that can effectively and rapidly treat the intramammary fistula and excessive healed cavities and cysts of the thoracic-abdominal wall.

In order to treat the patients with intramammary fistula and a large number of the mixture of PAAG and necrotic and degenerative tissues in the thoracic-abdominal wall, this study intends to design a new method for closing the subcutaneous fistula, blocking the excessive channels of the cavities and cysts between the chest and abdomen walls and taking the effective measures as soon as possible to eliminate further damage to the tissues and speed up healing of the cavities and cysts in the thoracic-abdominal wall. In this paper, 60 patients receiving the new treatment method in our orthopedic unit were selected, and the new treatment method was detailed as follows: sub-areolar incision combined with surgery for inferior segment of mass was used to clean PAAG, remove denatured matter and thoroughly scrape the residual cavity, flowing mass and lacuna of the thoracic-abdominal wall, and the suture method was adopted for closing the



**Figure 2.** Comparison of the two surgical methods for treatment of huge cavity in the thoracic-abdominal wall caused by PAAG displacement after augmentation mammoplasty (A: draining from the lower part of the displacement sac, B: multiple incisions for eliminating PAAG and lesions and closing the fistula).

intramammary fistula. Moreover, the residual cavities were scraped, and the wound area was washed with the drug for days, and negative pressure drainage of exudate was conducted at multiple parts. Meanwhile, 42 patients only undergoing surgery for inferior segment of mass without closure of the fistula were compared. The new method, which had better treatment efficacy and showed obvious advantages in decrease of the drainage volume and of lesion cavity size of the thoracic-abdominal wall as well healing time and relapse, is worth of being generalized.

#### Materials and methods

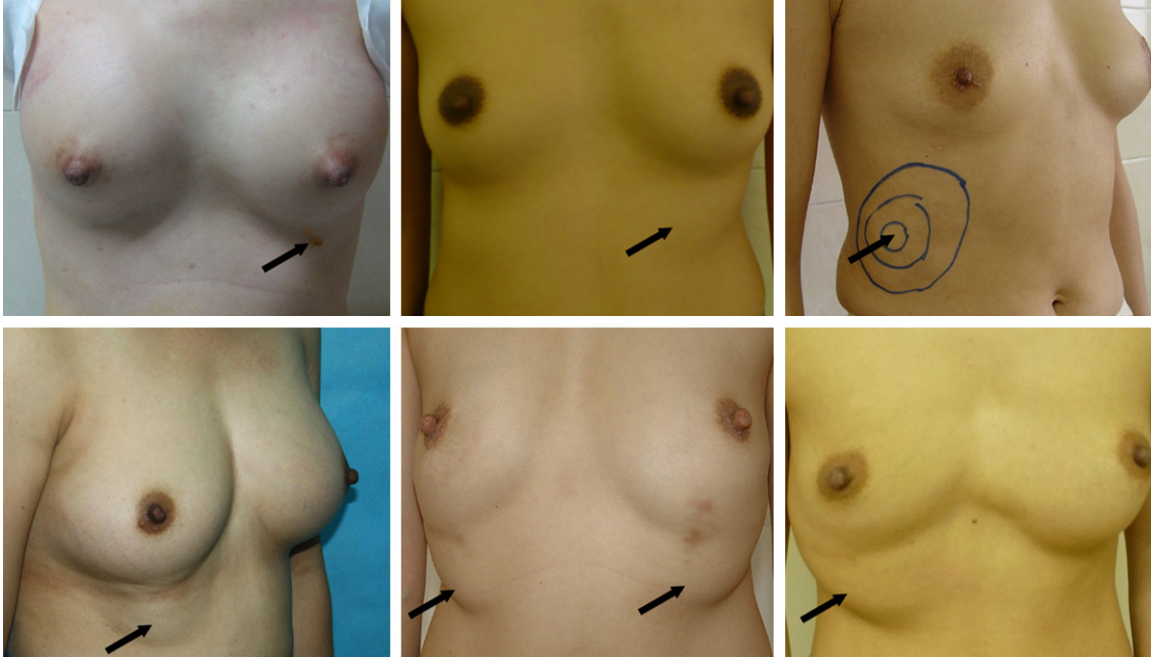
**Clinical materials:** 102 patients who were diagnosed definitely with PAAG mixture displacement in the thoracic-abdominal wall after augmentation mammoplasty with PAAG (trade name: Interfall) injection underwent the surgery in our orthopedic unit from January 2010 to March 2014. Among them, 60 patients received the new treatment method with detailed steps as follows: subareolar incision combined with surgery for inferior segment of mass was used to clean PAAG, remove denatured matter and

thoroughly scrape the residual cavity and the flowing mass and lacuna of the thoracic-abdominal wall, and the suture method was adopted for closing the intramammary fistula; meanwhile, 42 patients only undergoing surgery for inferior segment of mass without closure of the fistula were compared. Finally, we analyzed the local and systemic symptoms with the pathological manifestations after augmentation mammoplasty with PAAG, and explored the cause for the symptoms and the impact of the injectant on the human body. This study has been approved by the Ethics Committee of Southwest Hospital. Based on the ethical principles, all the patients had signed the informed consent form.

**Inclusion criteria:** the patients displaying failure in controlling the local symptom and recurrent cyst and mass in the thoracic-abdominal wall after treatment in the hospitals, or those having spreading PAAG displacement for more than two months. Excessive cysts and masses formed in the armpit and the thoracic-abdominal wall, and subcutaneous fistula connecting the thoracic-abdominal wall appeared in inframammary fold and flowing deposition of the



## PAAG mixture displacement



**Figure 3.** PAAG displacement appears in breasts and spreads towards abdominal wall due to improper aspiration.

mixture of PAAG and necrotic and degenerative tissues was found to form extensive flowing masses (**Figure 1**).

### *Surgical method for cleaning*

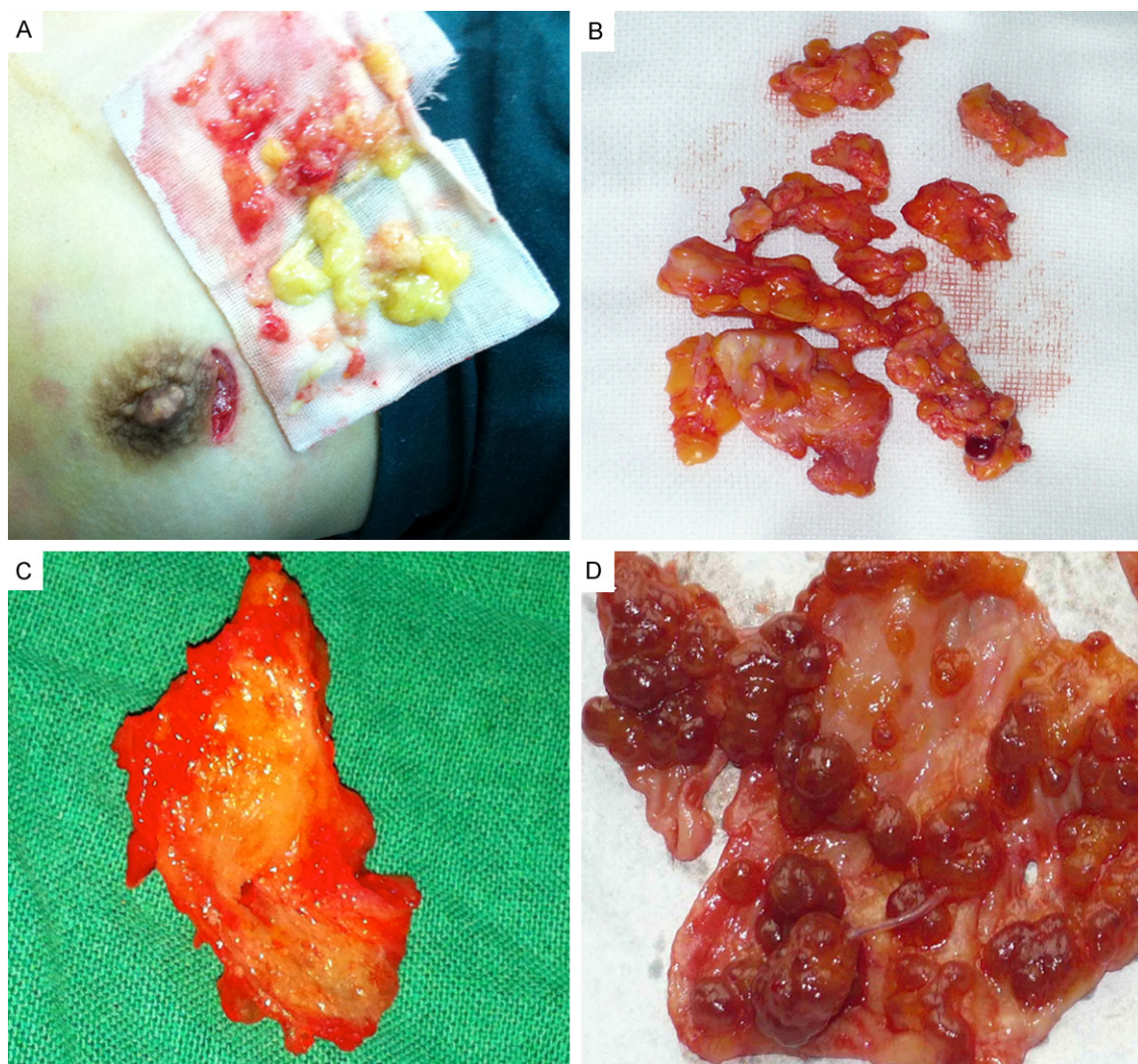
Preoperative subcutaneous puncture was adopted to explore the PAAG cavity, and the displacement scope was detected and marked by using B ultrasound or MRI, thus finding the location and size of the fistula at the junction of the inferior margin of the breast and the abdominal wall. A about 2-3 cm subareolar incision was made in the local diffusion area of the breast of 60 patients receiving the new method, and the tissues around the breast were separated inwards along the edge until the inferior pole to find the external wall of PAAG-induced sac and capsule. The incisions of different sizes were made underneath the sac for the patients with PAAG displacement into the thoracoabdominal wall. A detacher was inserted into the lacuna by the operator. Thereby, all PAAG sacs were fully dissociated (endoscope was used for guidance if necessary) to completely eliminate PAAG of the cysts and strip the necrotic tissues on the cyst wall. Furthermore, the special curet was adopted to thoroughly scrape the degenerative tissues until hydrogel compositions were invisible to the naked eyes or the fresh and healthy tissues were exposed, and the cavity was thoroughly washed with

plenty of saline. Meanwhile, the tissues of the anterior and posterior wall of the fistula mouth at the junction of inferior margin of the breast and the abdominal wall were sutured to close this channel. Subsequently, the negative pressure drainage tube was placed at the subareolar margin and the low part of the incision in the cavity of the abdominal wall (**Figure 2**). After surgery, the cavity was washed repeatedly with antibiotics plus saline after adequate drainage, gradually closing the residual cavity.

42 patients of the control group also underwent the surgery for cleaning. The key differences were that, for PAAG mixture exceeding the breast and migrating to the abdominal wall and other parts, an incision was made at the low part of the mixture sac, draining PAAG materials from the breast and washing the degenerative tissues of the sacs. While the fistula connecting the breast and the abdominal wall was not sutured and closed. Moreover, a drainage tube was placed via the inferior margin of the incision for drainage of the exudate, and pressure bandaging was performed to eliminate the flowing lacuna of the thoracic-abdominal wall.

### *Pathological examination*

All the patients signed the consent form. During the surgery, the 2×3×3 mm<sup>3</sup> specimen from the



**Figure 4.** PAAG leads to tissue infection, degeneration, necrosis, tissue Granuloma and abnormal nodules (A: chronic infection; B: degeneration of tissue; C: destroyed layers of tissue and necrosis of cells; D: formation of granulomas and abnormal nodules).

margin of the lesion was cut for pathological examination. Six months after the surgery, no displacement and relapse of masses in the thoracic-abdominal wall was found in the process of follow-up visit. A  $2 \times 3 \times 3 \text{ mm}^3$  tissue specimen obtained using a biopsy needle was embedded in paraffin and sectioned routinely, and then it was marked, positioned and observed under a microscope after H.E staining.

#### *Postoperative treatment and follow-up*

In clinical practice, the surgical efficacy for removal of PAAG and standard control of infection was evaluated according to the subjective

statement of the patients and the effectiveness of postoperative wound healing by a doctor. The patient was cured in case that no defects in the breast shape and anteroposterior and lateral view, no visible malformation in the body by naked eyes and no relapse of the lesion were found, otherwise, further treatment or surgery is needed.

#### *Statistical analysis*

Data were expressed as means  $\pm$  standard error (SE). Statistical differences among the mean values of multiple groups were determined using analysis of variance followed by



Student's *t*-test;  $P < 0.05$  was considered statistically significant.

## Results

### *Clinical symptoms*

42 patients of the control group included 15 cases with PAAG displacement in one breast and 27 cases with PAAG displacement in both breasts (mean age: 28 (21-49) years) (**Figure 3**). At day 570-1621 (mean: 1057), they were found to have PAAG displacement and felt swelling pain accompanied by irregular subcutaneous masses, and the local swelling had lasted for one to thirteen months. The patients did not exhibit improved condition and suffered from recurrent subcutaneous masses, which manifested as alternately presenting of progressive enlargement with temporary regression and shrinkage of the affected breast, and swelling pain or fever, obvious fluctuation when touching. Moreover, cysts and nodules of different sizes can be touched in the breast. The longer the course of the disease was, the more serious the condition of PAAG exceeding the breast and migrating and spreading to other parts was. The mixture of intramammary PAAG and degenerative and necrotic tissues diffused into the loose connective tissues and fat layer of the armpits, thoracic wall, upper and lower abdominal wall along subglandular space, thus causing the multiple metastatic sacs in the whole body. In severe cases, the cavity gaps of the entire armpit, thoracic wall and upper and lower abdominal wall were connected together via the fistula to form a huge subcutaneous hole with the area of more 113-341 cm<sup>2</sup>. The mixture of plentiful PAAG and degenerative and necrotic tissues flowed down and ruptured at the weak skin of the lower part of the abdominal wall to produce the multiple ulcers and fistulas in the whole body. B ultrasound or MRI in our hospital showed that the injection materials and the infected tissues gathered in retromammary space, some of which penetrated the pectoralis major.

In the new method group, 18 patients suffered from PAAG displacement in one breast, and 42 cases in both breasts, with age of 31(20-55) years. PAAG displacement appeared at day 619-1653 (mean: 1069) after augmentation mammoplasty, and the local swelling had lasted for two to sixteen months; the area of the

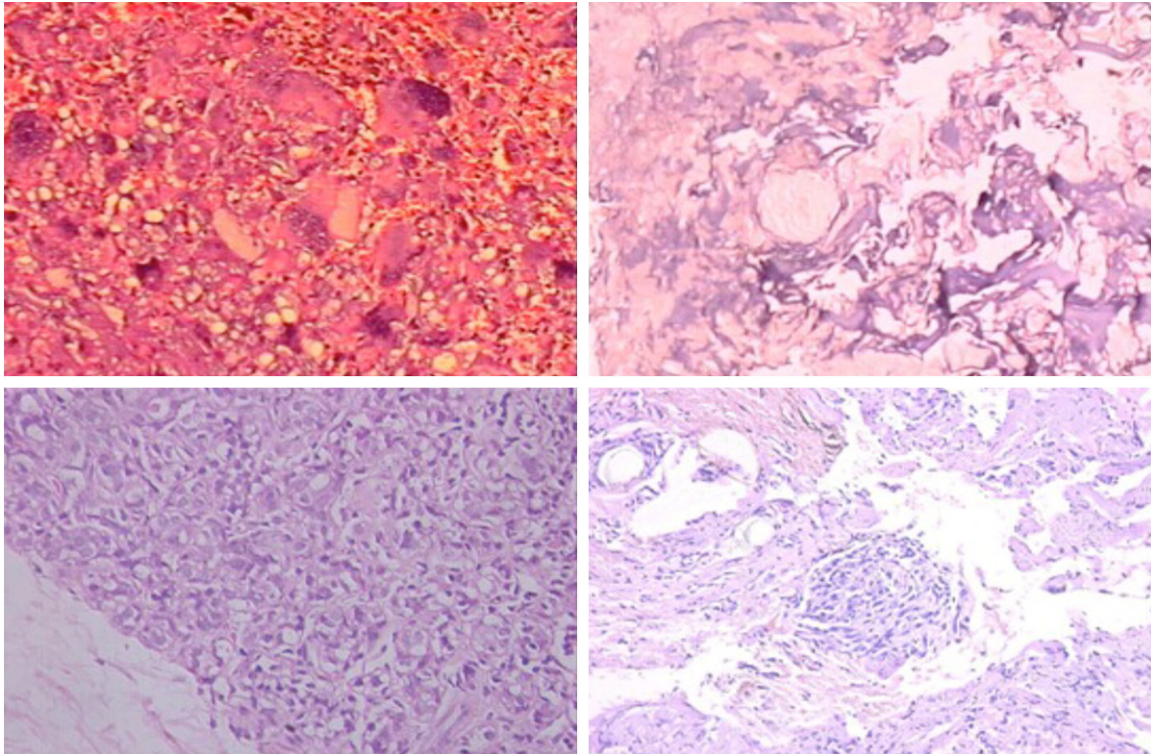
cavity was more than 186-332 cm<sup>2</sup>. Compared with the control group, this group exhibited roughly similar conditions including PAAG displacement part area, mass formation of the thoracic-abdominal wall and severity of the fistula when visiting the doctor, and had undifferentiated courses of the disease.

### *Surgery findings*

PAAG showed "roe-like" milky fine particles and was mixed with the necrotic fluid to form the sacs of different sizes in the subcutaneous layer, gland layer and muscular layer. Some PAAG particles adhered to the mammary glands in the internal wall and connective tissues and showed gelatinous degeneration, while some PAAG-induced lesions reached the pectoralis major. The sinus tract in it led to the armpit and sternum, involving multiple lacunas in which there were a lot of granulated injectant and necrotic tissues. In the patients displaying that PAAG exceeded the breast and spread to other parts, diffused PAAG particles were mixed with necrotic and degenerative tissues to become the fluid without fixed form, and they migrated and invaded towards the subcutaneous tissue clearance of the armpit, chest and abdomen. Finally, they deposited in the loose connective tissues and fat layer on the surface of the sarcolemma. Granuloma and chronic fibrotic lesions caused by stimulation of the inflammation can be seen everywhere. In addition, the fat layers in these areas were broken and absorbed to form a huge cavity (**Figure 4**).

### *Pathological examination*

Under a microscope, PAAG was purple-blue irregular foreign body and exhibited the following features: a large number neutrophils, lymphocytes and degenerative cells formed unstructured tissues, thereby becoming the typical infected lesion. Many purple-blue foreign bodies caused that the normal organization structures were occupied. PAAG particles integrated with the degenerative cells, and there were porridge-like degeneration, fat cell degradation, connective tissue proliferation, fibrosis and capsule wall thickening to form the chronic granuloma. The mammary glands and glandular tubes were affected, and PAAG particles of varying quantities in and around the glandular tubes blocked and closed the lumens, and oppressed the canals, thus causing the



**Figure 5.** Pathological examination showed accumulation and effusion of inflammatory cells, gathering of phagocyte and nodules of giant cells in the tissue.

infection and degeneration of the glandular tubes (**Figure 5**).

#### *Surgical results*

In all the 60 patients receiving the new treatment method, the healthy mammary glands and fat tissues until the external capsule of PAAG-induced sacs were separated through subareolar incisions. After opening the cavity, the flowing mixture was drained and sucked completely, and all the PAAG-induced sacs were stripped fully and cleaned. Besides, as for PAAG spreading into the abdomen, the position of the sac or fistula mouth was based on to enter the lesion layer of the abdominal wall through the inferior area or the low part of anterior superior spine. Thereby, the visible necrotic and degenerative tissues were cleaned up, while completely scraping the unhealthy components and clearly exposing the fresh and healthy tissues. An endoscope can be used for guidance if blind operation was inconvenient so as to thoroughly eliminate the residual mixture. After repeated and thorough washing, the patients were found to have even bleeding points on the wound and fresh tissues without

residual mixture. Inferior margin wall of the breast.

In the control group, an incision was made at inferior margin of the masses to successfully enter the lesion layers of the abdominal wall via the low part, thus separating the fat tissues until PAAG-induced sacs. After opening the cavity, the flowing mixture was drained and sucked completely, and all the PAAG-induced sacs were stripped fully and cleaned. The channel or sac in the lesion layer of the abdominal wall and the fistula position connecting the abdominal wall at the inferior margin of the breast was adopted for a reference to enter smoothly the sac of the breast. Washing was performed using a suction apparatus until that the drained liquid was clear and no visible PAAG particles were found. A drainage tube was placed after surgery.

#### *Treatment effect*

60 patients receiving the new treatment method started exhibiting signs of healing at 2 weeks, which manifested as shrinkage of the multiple flowing masses of the thoracic-abdom-

inal walls, reduction of liquid drainage and decrease of the lesion scope. The percentage of liquid drainage reduction and lesion size decrease was 82% and 80%, respectively. While in 42 patients of the control group, the synchronous percentage of liquid drainage reduction and lesion size decrease was 46% and 45%, respectively. There were significant differences between the two groups ( $P<0.01$ ). At four weeks, in some patients, the lacuna of the thoracic-abdominal wall disappeared completely, and the flowing masses and lesions had been removed, and the tissues of the anterior and posterior wall in the cyst and the cavity healed. According to the statistical results, the percentages of liquid drainage reduction and lesion size decrease were 97% and 98%, respectively, while these two values were 82% and 81% in 42 patients of the control group. There were significant differences between the two groups ( $P<0.01$ ). At 8 weeks, no one of these 60 patients was found to have enhancement and increase of the flowing masses and increase of exudate volume in thoracic-abdominal wall, and they all exhibited signs of rapid healing. The palpation of the breast showed no mass, cavity and fluctuation, and the secretions from the existing fistula mouth, nipple and incision reduced, and the discomforts disappeared. Re-examination was conducted by B ultrasound and the results displayed disappearance of the lesion and lacuna without hydrogel diffusion and liquid accumulation at the low part. Moreover, the tissues of the armpits and the thoracic-abdominal wall were close, and no residual cavity was found. The healing rate in the group using the new treatment method was significantly higher than that in the control group receiving aspiration and drainage.

## Follow-up

The healing time of the control group (average: 33 days) was obviously longer than that of the new treatment group (average: 21 days). All the patients were controlled in PAAG displacement after 6 months from start of treatment without residual lesion, relapse of flowing masses and excision of the breast. Nevertheless, the affected breast showed varying degrees of damage and deformation. Reexamination by using B ultrasound or MRI indicated that a small

amount of hydrogel spread in the breast tissues and pectoralis major.

## Discussion

PAAG consists of about 2.5% cross-linked polyacrylamide and sterile and pyrogen-free water [17]. Some studies showed that PAAG was non-cytotoxic and non-carcinogenic after implanted into the soft tissues of the body or the breast [18, 19]. Meanwhile, it was also thought that PAAG would not affect the surrounding tissues, and does not decompose as no PAAG particles were found in the excreta [20]. The major problem of the filler is that the injectant cannot be completely removed in case of adverse reactions after injected into the body to leave the permanent danger. There was also reports of PAAG-induced inflammation and granulomatous reactions [21, 22]. Through observation for more than 10 years, we found that PAAG was worthy of attention as they might damage the surrounding tissues of the implantation site in women receiving augmentation mammoplasty with PPAG injection, such as hyaline change and necrosis of muscle fiber or hyperplasia and induration of peripheral fibrous tissues, and may cause higher complications [23, 24].

Among the serious complications after PAAG injection, PAAG displacement is the most prominent one and manifests as elevated masses outside the contour of the breast, displacement scope flowing upward to the axilla and diffusing down to umbilical plane and even groin, and exceeding posterior axillary line in the left-right direction [25, 26]. In the paper, 102 patients all exhibited the shocking complications of PAAG displacement that may cause serious damage to the parts and the whole body. It was reported that the proportion of PAAG displacement-induced distortion of the breast was up to 66.7% [27]. The main causes for the filling material (PAAG) displacement are detailed as follows: 1. Hydrophilia and flowability: PAAG after absorbing water has no fixed shape and easily migrates towards the axilla, thoracic wall and upper abdomen [22, 28]. 2. Infection: contaminated PAAG, relaxed operation in the aseptic technique and allergic reactions may cause infection. Once the site suffers from the chronic infection, sinus tract would form in the skin, healing would become impossible [29-31]. 3. Foreign body reaction: after injected into the



body, PAAG is surrounded by many macrophages and integrated with them to form a huge phagosome consisting of PAAG and many surrounding macrophage plasma membranes (called as foreign body giant cell). The formed phagosome would erode the surrounding normal tissues to result in degeneration, necrosis, dissociation and apoptosis, thereby losing the connection and supporting role of the structure [32]. 4. Peripheral nerve stimulation: the incidence of local pain is 86.6%. In particular, PAAG would gradually invade the pectoralis major and the intercostal nerve terminal branches to cause varying degrees of pain [33]. 5. Inflammatory factors: PAAG, which is non-biodegradable and potentially toxic and cannot be removed completely, may induce the excitation mechanism of the removal of foreign filling material in the body to cause gathering of metalloprotease in digestive systems, thereby decomposing the normal tissue structures [34].

However, the methods for thoroughly treating the huge cavity connecting the thoracic-abdominal wall caused by PAAG mixture displacement, reduce the damage of the toxic substances to the human and reach a rapid healing of the tissues are rare, and the efficacy is unsatisfactory [35-38]. At present, a new surgical method is needed to effectively treat the serious lesion connecting the thoracic-abdominal wall caused by PAAG mixture displacement [39]. 106 patients in this paper featured by longer course, serious condition of the disease and the lesions involving multiple parts of the body. In 42 patients of the control group, although the intramammary condition in the breast and the multiple parts had been controlled after an eight-week treatment, parts of the flow masses in the thoracic-abdominal were present, and the healing of the tissues exhibiting the displacement systems was slower. Some patients suffered from enlargement of the masses in the thoracic-abdominal again, increase of the drained exudate and sudden exacerbation of the condition after two weeks, and the tissue showed signs of healing after the surgical treatment for 2-3 times. In 60 patients receiving the treatment using the new method, signs of healing started to appear after two weeks, and the percentage of drainage liquid reduction from the thoracic-abdominal wall and lesion size shrinkage was 82% and 80%, respectively. While in 42 patients of the control group, the

two values was 46% and 45%, respectively. There were significant differences between the two groups. At four weeks, the percentage of the drainage liquid reduction of the group receiving the new method was 97%, and the healing rate in the lesions of the thoracic and abdominal wall was 98%; while the two values of the control group were 82% and 81%, respectively. From this, we can find significant differences between them. At eight weeks, 60 patients all exhibited accelerated healing and did not showed residual cavity. Through comparing the healing rates between the two groups, we can see that the new treatment method with multiple incisions had an obviously better effect compared with the control group.

The chronic fistula connecting the thoracic-abdominal wall formed by intramammary PAAG mixture displacement is the key cause for flowing masses and huge cavity of the thoracic-abdominal wall, while the successful closure of this fistula is an important measure and way to promote the healing. With stronger toxicity, the flowing mixture of the thoracic-abdominal wall would erode and break the healing capacity of the internal wall of the fistula after repeated infiltration [40, 41]. The fat layer of the abdominal wall accounts for a large proportion and the organizational structure is relaxed. Once the flowing mixture exceeds the inframammary fold with compact structure, and migrates and spreads to other parts, the fat layers of these regions would be broken and absorbed to form the huge cavity. Aiming to the damage mechanism above, in this paper, we adopted the new method to create an enabling environment for healing of the cavity in the abdominal wall, thus accelerating the treatment of inflammation. Compared with 42 patients of the control group, 60 patients receiving the new treatment had faster drainage volume reduction of PAAG mixture decreased, larger drainage speed and rapid shrinkage of mass and the cavity in the thoracic-abdominal wall; besides, they displayed lower relapse proportion, less frequent debridement and better healing effect. It has been confirmed that the new method could obviously improve the success rate in completely closing the intractable and chronic fistula of the thoracic-abdominal wall, and promote the recovery of the huge and necrotic lacuna connecting the thoracic and abdominal

wall due to PAAG mixture displacement. During the six-month follow-up visit, no patients experienced relapse of the above-mentioned condition, and they all obtained satisfactory outcomes. Hence, the new method is worth to be popularized.

### Conclusions

The new method of subareolar incision combined with surgery for inferior segment of mass to clean the mixture and thoroughly eliminate the lacuna of the thoracic-abdominal wall as well as suture to close the intramammary fistula can improve the treatment efficacy.

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### Disclosure of conflict of interest

None.

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