

Mesh erosion after pelvic reconstructive surgeries

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ABSTRACT

الأهداف: نقل تجربتنا في تآكل رقعة بولي بروبين المستخدمة في العمليات الجراحية لإعادة بناء الحوض ومناقشة التغيرات النسيجية لتآكل الرقعة.

الطريقة: أجريت دراسة استيعادية لعدد 128 مريض خضعوا لعمليات جراحية لإعادة بناء الحوض باستخدام رقعة بولي بروبين خلال الفترة من مايو 2006 إلى مايو 2009م - قسم النساء والتوليد - مستشفى رينمين التابع لجامعة ووهان - هوبي - الصين. جمعت البيانات المتعلقة بالتغيرات الديموغرافية للمريض، وملاحظات العملية الجراحية، والمتابعة.

النتائج: بلغ معدل وقت المتابعة لـ 128 مريض 15.2 (1.3-60) شهر. تم تشخيص إصابة 7 مريض بتآكل الرقعة المهبلية (رقعة بروبين) و عانى مريض من تسرب متعلق بالرقعة. بلغ معدل وقت الانحراف المعياري في تآكل الرقعة 9.1 ± 7.6 شهر. تمت معالجة جميع المرضى وعددهم 7 بالجراحة. كانت الانتهابات الحادة من أهم التغيرات النسيجية في النسيج المتآكل.

خاتمة: تحدث معظم حالات تآكل رقعة بولي بروبين خلال العام الأول بعد العملية. يعد إزالة الرقعة من العلاج الفعال لتآكلها. نحتاج إلى المزيد من الدراسة لتحديد فيما إن كانت رقعة البولي بروبين تؤدي إلى حساسية مفرطة.

Objectives: To report our experience on the erosion of polypropylene mesh used in pelvic reconstructive surgeries, and to discuss the pathological changes of mesh erosion.

Methods: We conducted a retrospective study of 128 patients receiving pelvic reconstructive surgeries with polypropylene mesh from May 2006 to May 2009 in the Department of Gynecology and Obstetrics, Renmin Hospital of Wuhan University, Hubei, China. Data regarding patient demographics, operation notes, and follow up were collected.

Results: The mean follow-up time for the 128 patients was 15.2 (1.3-60) months. Seven patients were diagnosed with vaginal mesh erosion (Prolene mesh), and one of them suffered from anaphylactoid

breakout related to the mesh. The mean (\pm standard deviation) time occurring in the mesh erosion was 9.1 ± 7.6 months. All the 7 patients were treated with surgery. Chronic inflammation was the main pathological manifestations in the eroded tissue.

Conclusion: Most cases of polypropylene mesh erosions occur within one year postoperatively. Removal of the mesh could be the best therapy for mesh erosion. Further study is needed to determine if the polypropylene mesh induces supersensitivity.

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In the aging society, more and more women suffer from pelvic dysfunction diseases. Pelvic organ prolapse (POP) is caused by a loss of support from the endopelvic connective tissue and pelvic floor musculature. Vaginal looseness is considered the anatomic defect, which leads to stress urinary incontinence (SUI). Eleven percent of women underwent surgeries for POP, or SUI in their lives. The aim of traditional pelvic reconstructive surgeries is to restore fascial support by suturing it back to its original position. However, the failure rate reaches up to 30%. As a reinforcement or replacement of natural structure, synthetic mesh has been used for many years to reinforce the pelvic floor in a primary or recurrent prolapse. The curative effect of synthetic mesh used in abdominal prolapse surgeries is definite. Tension free vaginal tape (TVT), a mid-urethral sling procedure with synthetic mesh introduced by Petros and Ulmsten, had been used widely, and has been proven to be as effective as Burch colposuspension.^{1,2} Various techniques with different types of mesh have been introduced for the anterior, or posterior vaginal repair.

Mesh erosion has become a recognized, but uncommon complication since the synthetic mesh material was typically used. Nygaard's³ review of 98 articles on abdominal sacral colpopexy reported the general mesh erosion rate was 3.4% in 2004. Visco et al⁴ reported mesh erosion rates as 3.2% in the abdominal sacral colpopexies, 4.5% in the abdominal sacral colpoperineopexies (abdominal suture), while 16% in the vaginal suture. The mesh erosion rate rose to 40% when the mesh was placed vaginally. The mean mesh erosion time postoperatively were 15.6 months (abdominal sacral colpopexies), 12.4 months (abdominal sacral colpoperineopexies), 9 months (abdominal suture), and 4.1 months (vaginal suture). The TVT has a lower urethral erosion rate compared to other traditional sling procedures with synthetic mesh. To date, TVT has been accepted worldwide because of its high success rates, and relatively less complications. The reported erosion incidence was from 0.3-23%, lower than the autologous material.⁵ The advantages of super strength, durability, easy availability, and versatility has to be balanced against an increased risk of infection and erosion compared to autograft. Both the cure rate and erosion rate are high in anterior vaginal repair with synthetic permanent mesh. We retrospectively reviewed the records of 128 patients who underwent surgeries with polypropylene mesh for POP, or SUI. The aim of our study is to report our experience on the erosion of polypropylene mesh and to discuss the pathological appearance of mesh erosion.

Methods. Between May 2006 and May 2009, 128 patients that underwent POP, or SUI surgeries in the Department of Gynecology and Obstetrics, Renmin Hospital of Wuhan University, Hubei, China, with Type I monofilament polypropylene mesh (Prolene mesh, Prolift pelvic reconstructive system, trans vaginal tension-free tape obturator system (TVT-O), Ethicon Inc., Neuchatel, Switzerland), including vaginal hysterectomies combined with anteroposterior colporrhaphy, laparoscopic sacral suspension, TVT midurethral sling, TVT-O and Prolift system procedure were included in the study. Patients with suspected or confirmed malignancy, metabolic, endocrine, hepatic, or renal diseases were excluded from the study. We reviewed medical records, intraoperation notes, and pathological reports for each patient, and analyzed those with postoperative mesh erosion. We evaluated their preoperative history, physical examination, and laboratory examination. The severity of POP was assessed by the International Continence Society (ICS), Pelvic Organ Prolapse Quantification (POP-Q) staging system in all patients. The demographic data of patients includes age, parity, vaginal estrogen therapy, tobacco

use, menopausal status, and body mass index. Data of surgical procedure, intraoperative complications, follow-up time, mesh-related complications were also collected.

An oral consent was obtained from each patient and we did not take extra blood or tissues from any patient. All we reviewed were the medical records. Ethical approval was obtained from the Research Ethics Committee of our hospital. Each patient received vaginal douche and intravenous antibiotics for 3 days before the surgery. Estrogen vaginal cream was used for patients with senile vaginitis for 5-7 days. Patients with uterovaginal prolapse received vaginal total hysterectomies combined with anteroposterior colporrhaphy, TVT-O, or Prolift procedure, and patients with vaginal prolapse and SUI received laparoscopic sacral suspension combined with TVT-O after a 3-day bowel preparation. In the anteroposterior colporrhaphy, the vagina was dissected carefully, and the bladder was separated from the vagina. The paravesical fossa was opened on both sides, and the mesh was then introduced tension-free. The mesh was cut to a proper size (6 cm in width x 15 cm in length), and prepared under strict aseptic conditions. The vaginal wall was sutured using catgut. Associated procedures include a concomitant vaginal hysterectomy, concomitant rectocele repair using synthetic mesh, or TVT-O. In the laparoscopic sacral suspension, the mesh was secured in the rectovaginal septum and vesicovaginal septum, and sutured periosteum above the first sacral vertebra with at least 3 permanent sutures. All the patients received intravenous antibiotics for 5-7 days after surgery. All patients were required to visit the clinic one month and 3 months after discharge, then return back for routine office follow-up every 6 months. Unrelated complaints and health care maintenance of patients were also observed. Pelvic examination was performed at each visit. Vaginal ultrasound was used to ensure the location of the erosion. The diagnosis of mesh erosion was based on the clinical symptoms and pelvic examination. Patients with mesh-related symptoms were managed initially with daily estrogen and antibiotic vaginal cream, regardless of menopausal, or estrogen status. The mesh was removed from patients who were found with mesh exposition in pelvic examination, or was insensitive to conservative therapy. Eroded vaginal tissue removed from each patient underwent biopsy with hematoxylin and eosin staining. Patients with mesh erosion were followed up for an extra 6-12 months after the mesh was removed.

Continuous data were analyzed using student t test if appropriate, and categorical data were analyzed using the χ^2 test by the Statistical Package for Social Sciences version 13.0 (SPSS Inc., Chicago, IL., USA). The statistical significance was defined as $p < 0.05$.

Results. Polypropylene mesh was used in all 128 patients. There was no statistical difference between age, parity, menopausal status, estrogen, smoker, or POP stage (Table 1). Forty-seven patients underwent anteroposterior colporrhaphy combination with vaginal total hysterectomy, and 3 had mesh erosion. Sixteen patients underwent anteroposterior colporrhaphy and 2 had mesh erosion. In sixteen patients that underwent anteroposterior colporrhaphy combined with vaginal total hysterectomy and TVT-O, and one of them had mesh erosion. Out of the 14 patients who underwent laparoscopicsacral mesh suspension combined with TVT-O, one had mesh erosion at 3 months postoperatively. No significant difference ($p>0.05$) was found between each procedure (Table 2). Erosion mesh is Prolene mesh, 6 cases in vaginal colporrhaphy and one case in sacral mesh suspension. During the follow-up period, 7 had mesh erosion with various symptoms. All the erosions were located in the vagina, and each patient with mesh erosion required mesh excision partly, or completely. The details of the erosion group are listed in Table 3. All the 7 patients had mesh erosion in the vaginal wall. The mean time to erosion for these 7 patients was 9.1 ± 7.6 months, ranging from 1-24 months. Erosion related symptoms including vaginal pain, discharge, bleeding, odynuria, and urgency appeared in these 7 cases. All the 7 patients needed surgery to remove the mesh partly or completely, because conservative therapy was not effective. Our conservative therapy involved excising the unabsorbed suture and the granulation tissue, vaginal antibiotics, and vaginal estrogen therapy.

A 71-year-old patient has to be mentioned here for a wheal all over the body in concomitance with the mesh. The wheal appeared at 2 months postoperatively pervading from limbs to all over the body, and did not disappear until the mesh was completely removed. The wheal could be induced after eating animal albumin

like prawn, or chicken. She underwent abdominal hysterectomy 20 years ago for ovarian benign tumor. She was never hyperergic to other things before the mesh was placed in the vagina. Her purulent discharge appeared extremely early just at one month postoperatively. Pathological reports of the 7 patients' eroded tissue were similar: chronic inflammatory cells (lymphocyte, mononuclear macrophage, neutrophil granulocyte, and plasmocyte) infiltrating the eroded tissue (Figure 1). Multinucleated giant cell and foreign-body granuloma was detected in one sample.

Discussion. Clinical characteristics of mesh erosion.

The characteristics of ideal mesh involve physical and chemical inertia, non-carcinogenicity, non-immunogenicity, robustness, cheap, anti-infection, and multiformity. It was introduced in the middle 1900s and the studies had never stopped since then. Prolene mesh is type 1 mesh. Mesh erosion is a special complication of synthetic mesh used in POP or SUI surgeries. An author reported that synthetic mesh erosion of sacro-colpopexy rate ranged from 0.8-12%.⁶ A multicenter study in Northern Europe on TVT reported no mesh erosion after 58 months follow-up.⁷ Approximately

Table 2 - Operation methods carried out for patients.

Characteristics	No erosion n=121	With erosion n=7	Erosion rate (%)	P-value
APC	14	2	(13)	
VTH+APC	44	3	(6)	
VTH+APC+TVT-O	15	1	(6)	
LSS+TVT-O	13	1	(7)	>0.05
TVT-O	6	0	0	
VTH+Prolift	21	0	0	
Prolift	4	0	0	

APC - anteroposterior colporrhaphy, VTH - vaginal total hysterectomy, LSS - laparoscopic sacral suspension, TVT-O - tension free vaginal tape

Table 1 - Demographics of 128 cases.

Variable	No erosion (n=121)		With erosion (n=7)		P-value
	Mean ± SD	95% CI (range)	Mean ± SD	95% CI (range)	
Age (years)	54.7 ± 13.4	52-57.1 (30-83)	51.7 ± 9.4	44-58.6 (44-71)	0.35
Parity	2.4 ± 1.5	2.1-2.7 (1-8)	1.9 ± 1.1	1.1-2.7 (1-4)	0.10
Menopausal, n (%)	67 (55.4)		3 (42.9)		0.78
Estrogen, n (%)	13 (11.1)		1 (14.2)		0.85
Smoker, n (%)	1 (1)		0 -		-
POP stage 2, n (%)	23 (19)		1 (14.2)		0.91
POP stage 3, n (%)	59 (49)		4 (57)		0.82
POP stage 4, n (%)	39 (32)		2 (29)		0.72
Follow-up time (m)	15.4 ± 8.5	13.9-16.9 (3-25)	11.9 ± 4.9	8.3-15.5 (5-20)	0.8

Data are presented as mean + standard deviation (SD [range]), or n (%). CI - confidence interval, POP - pelvic organ prolapse, m - months

Table 3 - Cases in the erosion group.

Patient number	Age, (years)	Parity	POP stage	Procedure	Location in the vagina	Symptom before treatment	Time to erosion, (months)	Treatment	Follow-up (months)	After surgery
1	46	1	4	VTH+APC+TVT-O	Anterior	Lower abdominal pain	13	Mesh excision	16	Normal
2	49	1	3	VTH+APC	Anterior	Vaginal pain	8	Mesh excision	10	Normal
3	71	4	3	APC	Anterior	Purulent discharge	1	Mesh excision (complete)	12	Normal
4	52	2	4	APC	Posterior	Vaginal pain	9	Mesh excision	11	Normal
5	44	1	3	LSS+TVT-O	Posterior	Sexual pain	3	Mesh excision	5	Normal
6	55	2	3	VTH+APC	Anterior	Odynuria, urgency	6	Mesh excision	9	Normal
7	45	2	2	VTH+APC	Posterior	Bleeding, rufous discharge	24	Mesh excision	20	Normal

VTH - vaginal total hysterectomy, APC - laparoscopic sacral suspension, TVT-O - tension free vaginal tape, LSS - laparoscopic sacral suspension

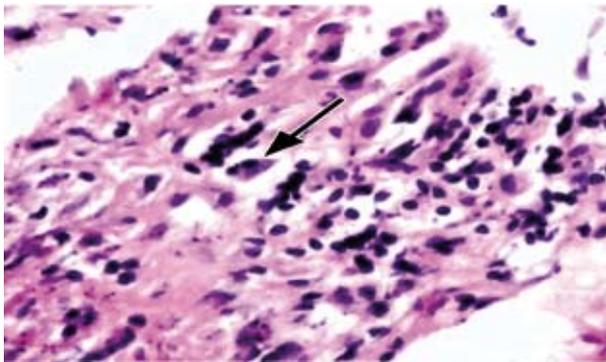


Figure 1 - Inflammatory cells infiltrating the vaginal wall tissue (20x10). The arrow points to a phagotrophic phenomenon.

2-12% of patients with anterior colporrhaphy received surgery to trim, or remove the mesh due to infection, or mesh erosion. The disparity of the mesh erosion could be due to the surgical technique. A vertical vaginal incision is considered to increase erosion rate of synthetic mesh. In this study, the erosion rate of different operations was 6-13%. Many retrospective studies have reported some possible risk factors of mesh erosion. Ahtari et al⁸ reported that age was an independent risk factor for mesh erosion. Deffieux et al⁹ also reported that age was an independent predictive factor of vaginal erosion, especially for those above 70 years old. Lowman et al¹⁰ reported that tobacco use was a risk factor for mesh erosion. His study showed that the erosion rate in smoking patients was 4 times higher than in non-smoking patients. Two comparative studies found that different mesh type had nothing to do with the incidence of vaginal mesh erosion in smoking patients.^{8,9} Thompson et al¹¹ reported concomitant hysterectomy caused a higher rate of mesh erosion (13.6 versus 0.7%). Culligan et al¹² also found that mesh erosion was related to hysterectomy. In contrast,

Brizzolara and Pillai-Allen⁴ found no mesh erosions in 60 patients who underwent hysterectomy, and one erosion in 64 patients (0.8%) with a previous hysterectomy. Wu et al¹³ found that concomitant hysterectomy with abdominal sacral colpopexy was associated with an increased risk of mesh erosion in women with estrogen therapy. However, hysterectomy was not a risk factor of erosion for women without estrogen treatment. Wu et al¹³ also reported that anterior vaginal wall imbrication with silk sutures increased the risk of erosion. The mechanism was unclear, however, tissue ischemia caused by imbrication and an inflammatory reaction caused by the silk sutures might be the 2 possible explanations, which cannot explain posterior erosion. The possible reason is the inherent nature of the anterior vagina, which makes the anterior vagina more susceptible to be eroded. It is hard to evaluate if the existence of other mesh simultaneously increases the occurrence of erosion. This study is limited by a small sample size, and the relative fact of mesh erosion is uncertain. Therefore, it is difficult to determine if erosion will happen to those patients nowadays without mesh erosion in the future.

In this study, all the erosions are located in the vagina, but what is the reason for this phenomenon? The real mechanism of erosion is still uncertain. Poor incorporation, infection, and excessive foreign body reaction are considered multiple factors for fibrous tissues. Fibroblasts and collagen were present in half of the specimens. The vagina is susceptible to infection due to its anatomical position. The rolling of the mesh caused by inadequate vaginal incision suturing may lead to vaginal pressure necrosis, wound infection, and impaired wound healing after infection. Therefore, the vagina seems to be eroded more easily. However, the possibility of a surgical error should also be considered, which is probably the major reason for vaginal erosion in some conditions. In this study, all the vaginal erosions

required mesh removal because conservative therapies were not effective. Different mesh had no significant different erosion occurrence. But in this study, all mesh erosions originated from the Prolene mesh. It was possibly because the Prolene mesh is much heavier than the Prolift mesh, but less flexible than the TVT-O mesh, which is unfavorable for the tissue to grow, but easy for infection.

Wheal-like erythra in erosion patient. In this study, one 71-year old patient suffered wheal-like erythra with skin itch as a simultaneous phenomenon all over her body postoperatively for more than 9 months, and the erythra did not disappear until the complete removal of the mesh. It seemed that the erythra was caused by the mesh, but the erythra could be induced by eating animal albumin like prawn or chicken. Anti-anaphylaxis was effective for the erythra. In the 6 months follow-up after removal of the mesh, the erythra never reappeared even though she ate prawn or chicken. Two laboratory examinations also suggested the possible relation between the polypropylene mesh and the erythra, however, in her specimens no eosinophil cell was found. The erythra may be concerned with the polypropylene mesh. This case indicates that the erythra is an anaphylaxis, but the anaphylactogen is not indefinite. One reasonable explanation is that the inflammatory, or foreign body reaction caused by mesh, sensitized the patient to animal albumin. The exact mechanism needs further studies.

Pathological appearance of vaginal tissue with mesh erosion. There are 4 stages of pathological changes after inserting the mesh: stage 1 (in a week) - instant inflammatory reaction, micrangium hyperplasia, granulation tissue and giant cells emerge around the mesh; stage 2 (1-2 weeks) - granulation tissue exists and vesicular tissue starts to form; stage 3 (2-4 weeks) - instant inflammatory reaction vanishes and micrangium reverts; stage 4 (after 4 weeks) - giant cell attacks and fibroplasias emerges on the surface of the mesh. In this study, surgeries to remove mesh were performed at least 3 months after pelvic reconstructive surgeries, in which the following were observed: chronic inflammatory cells infiltrate the tissue near the mesh, fibrous connective tissue hyperplasia and hemangiectasia can be detected in the submucous layer, vaginal wall endepidermis is parakeratotic and hyperplastic, and a foreign-body granuloma was found in one sample. It is not definite if these pathological changes of eroded tissue cause the pathological appearance. The polypropylene mesh used in pelvic reconstructive surgeries is considered nonabsorbable, nontoxic, and provides high tensile

strength for reconstruction. Mesh in tissue develops fibrous scarring in adjacent tissues, injuries to surrounding tissues, infection, and erosion, or even rejection.

In conclusion, most polypropylene mesh erosions occur within one year postoperatively. Removal of the mesh could be the best therapy for mesh erosion. Further study is needed to determine if polypropylene mesh induces supersensitivity.

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