Medicine

OPEN

Long-term infectious complications of using porous polyethylene mesh for orbital fracture reconstruction

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Abstract

Porous polyethylene is a widely used implants in orbital reconstruction, on which comprehensive clinical analysis, various treatments, and different prognosis according to specific classification principles on long-term complications have not been reported.

To investigate the new clinical symptoms, intraoperative findings, treatments, and outcomes of complications long period after previous surgery, resulting from the use of porous polyethylene mesh for orbital fracture reconstruction.

A retrospective study was conducted on 21 patients at the Department of Ophthalmology, Shanghai Ninth People's Hospital with orbital complications after orbital fracture reconstruction with porous polyethylene mesh for 4 ± 2.2 years from 2011 to 2013. These data included new clinical symptoms after previous surgery, computerized tomography data, intraoperative findings, treatments, and outcomes.

Data from 21 patients were analyzed in this study. Two patients received conservative treatment, while the other 19 patients underwent surgical approaches. Classification principles for orbital complications after orbital wall defect reconstruction with porous polyethylene mesh were formulated according to patients' new clinical symptoms, computed tomography (CT), and intraoperative findings after previous surgery. In the last follow-up, 19 patients (90.5%) were cured or improved according to our assessment principle. The follow-up ranged from 3 to 45 months (35 months in average).

According to specific classification for orbital complications resulting from the use of porous polyethylene mesh for orbital fracture reconstruction, various medical treatments should be carried out, and the prognosis may be different.

Abbreviation: CT = computed tomography.

Keywords: complication, orbital fracture reconstruction, porous polyethylene

1. Introduction

Porous polyethylene is a widely used implants in orbital reconstruction and contour reestablishment^[1] as micropores facilitate the growth of fibers and blood vessels through the material.^[2] Porous polyethylene has been used to mimic the structure of orbital floor and middle wall and has been reported to be safe and durable, whose indication is defects in orbital walls deserving relative low stress.^[3]

Various complications after implantation of porous polyethylene have been reported such as infection, exposure, and distortion.^[4,5] However, most of these foreign body reactions were discussed regarding facial contour reconstruction and ocular prosthesis implantation after eviscerations.^[6,7] Orbital floor fracture is the second most common type of midfacial

Medicine (2016) 95:25(e3819)

http://dx.doi.org/10.1097/MD.00000000003819

fracture and is often concomitant with defects in lamina papyracea.^[8] In the reconstruction of the orbital floor and middle wall structure, comprehensive surgery, from ophthalmic to nasal, and maxillary are required.^[9,10] In order to facilitate orbital volume recovery, multiple porous polyethylene meshes have been placed into the orbits by some surgeons, which can potentially increase the risk of dead space formation and infections around the implants.

From the report of Timoney et al,^[11] inflammatory giant cell reactions were observed in patients who underwent orbital fracture repairs with porous polyethylene implants, in which, foreign body granuloma formation was identified by H&E histologic sections.

To our knowledge, comprehensive clinical treatments and outcome observation according to specific classification on longterm complications of porous polyethylene mesh used for orbital reconstruction has not been reported. The aim of this study was to investigate various treatments according to specific classification principle of long-term complications of porous polyethylene mesh used for orbital reconstruction, and also to assess the outcome.

2. Methods

2.1. Ethical issues

The study followed the tenets of the Declaration of Helsinki, and the local ethics committee of our university approved the study protocol.

2.2. Epidemiology

In this retrospective study, data from 21 patients (21 eyes) with various orbital complications secondary to orbital reconstruction

Editor: Leonidas G Koniaris.

The authors have no funding and conflicts of interest to disclose.

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Received: 18 October 2015 / Received in final form: 13 March 2016 / Accepted: 9 May 2016

with porous polyethylene mesh presented to Shanghai Ninth People's Hospital from January 2011 to December 2013 were analyzed after approval from the internal review board.

2.3. Including and excluding criteria

Patients with orbital complications after fracture reconstruction with porous polyethylene mesh on middle wall and floor of the orbit were included in this study, while those who underwent reconstruction surgeries on other walls of the orbit or with other materials were excluded.

2.4. Obtained data

- 1. New clinical symptoms after previous surgery: eyelid edema, ectropion, chemosis, proptosis, impaired vision, restricted mobility, etc.
- 2. Local examination: otorhinolaryngological (accessory nasal sinuses) and ophthalmological examination.
- 3. Computed tomography (CT) data: horizontal, frontal, and sagittal position and cranalis-orbital-nasal 3-dimensional reconstruction.

2.5. Classification of disease

Referring to the Chandler classification for orbital complications of sinusitis to some extent,^[12] we formulate a specific version of that to clarify the intraoperative findings and CT images in our cases (Table 1). In short, type I, II, III, and IV represent local preseptal inflammation, diffuse septal inflammation mass, local preseptal abscess, and diffuse septal abscess.

2.6. Treatment

According to the specific version of Chandler classification mentioned above, various treatments including medical therapy,

Table 1

Classification principles for orbital complications after orbital wall defect reconstruction with porous polyethylene mesh (referring to the Chandler classification).

		Type I	Type II	Type III	Type IV
Symptoms	Eyelid edema	+	+	+	+
	Eyelid hyperemia	+	+	+	+
	Limitation of ocular movement	_	+	+	+
	Abnormal visual acuity	_	±	±	+
	Dystopia of eye	±	+	±	+
	Proptosis and chemosis	_	+	+	+
	Ectropion	_	±	±	+
	Ophthalmoplegia	_	_	_	+
CT or introperative findings	Orbital contents diffuse edema	_	+	_	+
	Mass around implants	_	±	+	+
	Mass away from the implants	_	_	_	+
	Poorly vascularized implants	_	_	+	+
	Fragile implants	_	_	_	+
	Pus between periorbita and implants	_	_	+	±
	Pus within the orbital tissues	_	_	_	+
	Implants partly encapsulated by cyst	-	_	+	±

CT = computed tomography.

drainage as well as surgeries were performed separately or coordinately. Briefly, patients of type I received only conservative treatments, while those of type II, III, and IV were presented to surgical treatments together with antibiotics (Table 2).

1. Conservative treatments for type I patients:

Second-generation cephalosporin at a dose of 80 mg/kg/day intravenously together with antiinflammatory agents and decongestants for a duration of 14 days.

2. Comprehensive approaches for type II, III, and IV patients: Step 1: Preoperative medicine treatment

Preoperative 2nd-generation cephalosporin at a dose of 80 mg/ kg/day intravenously together with antiinflammatory agents and decongestants for a mean duration of 3 days.

Step 2: Drainage and surgical intervention

Drainage and surgical intervention were performed based on CT scan showing subperiosteal or orbital cyst/abscess and failure to improve orbital or systemic symptoms clinically within 72 hours by conservative treatment. Drainage was performed at the apertura sinus maxillaris via transendoscopic approach. Porous polyethylene mesh extirpation and secondary titanium mesh implantation were performed via open approaches by trans-conjunctival approach or subciliary approach.

Step 3: Chloromycetin and saline irrigation

Chloromycetin and saline irrigation were performed in the interval of porous polyethylene mesh extirpation and closing of orbital wounds intraoperatively, also performed after surgery during daily dressing changes.

Step 4: Postoperative medicine treatment

Oral antibiotics: shifting from intravenous to oral antibiotics after surgical treatments together with antiinflammatory agents and decongestants for a duration of 14 days.

2.7. Assessment principles

In the last follow-up, patients with no symptom or imaging manifestation of local inflammation or infection were defined as CURE; patients with partial symptoms but no imaging manifestation of local inflammation or infection were defined as IMPROVEMENT; and other patients were defined as ELSE.

2.8. Pathological examination and bacterial culture

Pathological examinations were performed on all tissue around the extirpated polyethylene meshes. Bacterial culture of cyst/ abscess fluid was carried out during the surgery.

3. Results

Twenty-one patients were presented to Shanghai Ninth People's Hospital over the 3-year period with orbital complications secondary to orbital fracture reconstruction with porous polyethylene mesh.

able	92					
Surgical procedures according to our classification principle.						
	Number	Surgical procedure				
Type I	2	Drainage				
Type II	5	Open orbital surgery + simultaneous titanium mesh implantation				
Type III	8	Open orbital surgery + drainage + secondary titanium mesh implantation in 3 or 6 months				
Type IV	6	Open orbital surgery + drainage + secondary titanium mesh implantation in 3 or 6 months				

Age of the patients ranged from 19 to 45 years with a mean age of 33 ± 8.4 years. All patients were adults. Thirteen patients (62%) were male while 8 (38%) were female. The right orbit was involved in 14 cases (67%) while the left orbit was involved in 7 cases (33%). Porous polyethylene meshes were implanted into the patients' orbits 4 ± 2.2 (mean \pm SD) years before they were presented to our department due to orbital complications.

3.2. New clinical symptoms and intraoperative findings after previous surgery

Poorly vascularized multiple porous polyethylene meshes with cyst/abscess were seen in some cases inside the orbits, which can potentially increase the risk of dead space formation and infections around the implants (Figs. 1 and 2).

According to the classification principle in Table 1, there were 2 patients in type I (9.5%), 5 patients in type II (24%), 8 patients in type III (38%), and 6 patients in type IV (28.5%).

3.3. Management

Patients in type I with only edema and hyperemia of the eyelid started with medical treatment and responded well to antibiotics, the other patients in type II, III, and IV were presented for surgical treatment after their failure to improve orbital or systemic symptoms clinically within 72 hours by conservative treatment and received open approach surgeries with drainage.

Endo-nasal drainage was performed at apertura sinus maxillaris via a transendoscopic approach. Porous polyethylene mesh extirpation and secondary titanium mesh implantation were performed via open approaches by trans-conjunctival approach or subciliary approach. Note that simultaneous titanium mesh implantation for orbit reconstruction could only be performed on the patients without pus within the orbits or between the periorbit and implants (type II), while the type III and type IV patients received a 2nd orbital reconstruction surgery with titanium mesh implantation at 3 to 6 months after the porous polyethylene mesh extirpation (Figs. 3–5 and Table 2). Symptoms and CT images in all 21 patients were well documented. Eyelid edema, ectroption, dystopia, and periorbital abscess were shown in Figs. 6–8.



Figure 1. Intraoperative finding: the use of multiple porous polyethylene meshes in order to facilitate orbital volume recovery.



Figure 2. Intraoperative finding: porous polyethylene meshes were poorly vascularized.

3.4. Pathological examination and bacterial culture

Among the 19 patients underwent surgeries (type II, III, and IV), 13 of whom presented a pathological diagnosis of lymphocytic infiltration. None of the bacterial culture showed a positive result, even in the case with strong odor during the operation.

3.5. Outcome and follow-up

At the last follow-up, all patients of type I and II were in CURE group; half of type III patient were in CURE group and half in IMPROVEMENT group; and no patients of type IV were in CURE group, among whom 4 of whom were in IMPROVE-MENT group and other 2 were in ELSE group (Table 3). The follow-up ranged from 3 to 45 months (35 months in average). None of the patients needed removal of the newly placed titanium implants during the follow-up.

Nineteen patients (90.5%) had a good outcome (CURE or IMPROVEMENT) according to our assessment principles



Figure 3. Computerized tomography image before surgery (type III): multiple porous polyethylene meshes were applied to reconstruct the left orbit and recover the volume of the orbit.



Figure 4. Computerized tomography image 1 month after surgery (without titanium mesh implantation): multiple porous polyethylene meshes adjacent to the defect in the inferior orbital wall were extirpated.

shown in Section 2. Eleven patients (52.4%) were in the CURE group, and 8 (38.1%) were in the IMPROVEMENT group. In the IMPROVEMENT group, 1 patient remained proptosis and dystopia of the eye (4.8%), 2 patients (9.5%) remained orbital mobility restriction and diplopia, 3 patients (19%) suffered from diplopia, and 2 patients (9.5%) remained with eyelid edema and chemosis.

Two patients (9.5%) continued to suffer from refractory maxillary sinusitis, diplopia, and abnormal visual acuity, which required a 2nd surgical intervention of total ethmoidectomy with middle meatal antrostomy to clear residual sinusitis but refused further treatments. These 2 patients were classified into the ELSE group according to our assessment principles shown in Section 2.

4. Discussion

From our experience from treating those 21 patients who suffered from orbital complications after primary orbital fracture



Figure 5. Computerized tomography image 6 month after surgery (right after the secondary surgery in our department for titanium mesh implantation): bony defect in the inferior orbital wall was repaired by titanium mesh anatomically.



Figure 6. Complication: ectropion and dystopia.

reconstruction with porous polyethylene, we made the following conclusions:

- 1. Eikonic enlargement of the inflammatory mass indicates exenteration for mass removal, implants extirpation. Cases with visual affection or mobility restriction advocate for surgical intervention to deal with both the affected sinuses and nearby orbit. This opinion was supported by other researchers.^[13,14]
- 2. Antibiotics are efficient in early stages (type I), while patients of other types deserve additional surgical intervention, nasal decongestant, and mucolytics. Intravenous antibiotics should be administered together with drainage, although theoretically, intravenous antibiotics can penetrate the abscess. This could be explained by purulent milieu's protection function on microorganisms by enzymatic degradation of antibiotics.^[15,16]
- 3. Secondary titanium implantation should be performed simultaneously on type II patients, while patients of type III



Figure 7. Complication: eyelid edema.



Figure 8. Computerized tomography image: periorbital abscess.

and IV should receive another surgery for orbital reconstruction with titanium mesh after 3 to 6 months.

- 4. Patients of type I, II, and III had relative good prognosis, while most of whom (11/15) received complete recovery. However, patients of type IV may receive unsatisfactory results, that two thirds of whom were partly recovered and the other one third were ineffectual. We deduce that diffuse septal abscess (type IV) may affect orbital function severely and permanently, even with subsequent surgeries.
- 5. Multiple porous polyethylene meshes application is not recommended for orbit reconstruction, as it may potentially increase the risk of dead space formation and inflammation/ infections around the implants.

Porous polyethylene is commonly used in orbital defect repair, anophthalmic reconstruction, and also facial contour surgeries.^[11] As orbital implants for fracture reconstruction, biocompatibility, available in several shapes, sizes, and insoluble characteristics are commonly accepted advantages of porous polyethylene.^[17]

Among the patients included in this study, cysts, abscess, exposure, and unfavorable vascularization of porous polyethylene meshes were observed, possibly due to dead space formation arising from the implantation of multiple meshes or intermittent sinusitis after facial trauma and former orbital fracture surgeries. Orbital complication accounts for around 80% of complications caused by acute sinusitis.^[18] Moreover, sinusitis is usually under treated after surgeries operated by nonotolaryngologists leading to a variety of complications. In our team, orbital fracture patients combined with accessory nasal sinus trauma or signs of inflammation before or after surgeries would routinely receive nasal decongestants, mucolytics, and saline irrigation to promote sinus drainage through our cooperation system with ear-nose--throat doctors. Swift et al^[19] reported that the ethmoidal and maxillary sinuses were most frequently involved in orbital complication cases coincides with our study.

Assessment in the last fol	llow-up.	
Table 3		

	Total	CURE	IMPROVEMENT	ELSE
Type I	2	2	0	0
Type II	5	5	0	0
Type III	8	4	4	0
Type IV	6	0	4	2

CURE = patients with no symptom or imaging manifestation of local inflammation or infection in the last follow-up, IMPROVEMENT = patients with partial symptoms but no imaging manifestation of local inflammation or infection in the last follow-up, ELSE = patients who were not in group CURE or IMPROVEMENT.

Complications associated with the use of porous polyethylene orbital meshes include edema and hyperemia of the eyelid, ectropion, limitation of ocular movement, proptosis, abnormal visual acuity, chemosis, ophthalmoplegia, and abnormal mass (computerized tomography results). Intraoperatively, pus was collected between periorbit and implants (type III), or within the orbital tissues in some severe cases (type IV). From our experience, such kind of orbital inflammation resulting from foreign body reactions usually occurred in the distant postoperative period, which coincides with some other researcher's opinion.^[11] However, on the part of the patients, these complications aggravate largely due to ignorance and under treatment, while some sinusitis signs could be misunderstood as common cold. On the part of the clinicians, delayed or missed diagnosis would also be a leading reason for the exacerbation.^[20]

Comprehensive orbital examination and CT scan are mandatory for diagnosing and staging these patients. Periorbital complications after orbital reconstructive surgeries, ethmoidal and maxillary sinusitis were defined by the presence of opacification or air fluid level on CT scan. Furthermore, a homogeneous opacity which might be demonstrated as cellulitis or even an indication of early abscess formation would be dangerous. This coincides with Skedros Demetrios et al^[21] who concluded that CT scans were able to diagnose 80% of subperiosteal abscess cases.

In this study, patients were grouped depending on the site of complication (preseptal or postseptal, in other words, periorbital or orbital), and the result of pus collection. However, some details like pus infiltration and exact sites of cyst could only be described intraoperatively. For that reason, our specific version of Chandler classification was defined as a combination of clinical symptoms, CT imaging, and intraoperative findings, which were newly found after previous surgery. For example, part of the characteristic of type IV patients (diffuse orbital abscess group) was proptosis, chemosis, and ophthalmoplegia, which distinguish this type from type III ones (local periorbital abscess group). To emphasize, type IV patients should be treated in a much aggressive way to prevent fatal complications like cavernous sinus thrombosis, meningitis, and brain abscess.^[22]

Penetration of the blood clot inside the pores of the porous polyethylene is vital for the stability of the material with adjacent growing tissues.^[23] However, in some of our patients in type III and type IV, the porous polyethylene mesh was fragile and not well vascularized, which may be a potential reason for dead space formation and following complications.

In this study, pathological diagnosis showed inflammation sign in some of the cases, while all bacterial culture results were negative. In recent research, *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* are some of the most popular pathogens in infectious sinusitis.^[24] However, data of this kind in orbital disease were not clarified.

Up to our knowledge, this is the 1st study providing comprehensive analyses on long-term complications after orbital wall reconstruction with porous polyethylene. In addition, we deduce that different types of patients by Chandler classification should receive various treatments and may be different in diagnosis. The limitation of this study was the sample size and setting of control groups. Additionally, much work should be done to identify the type of pathogen in orbits for reasonable antibiotic application.

Acknowledgments

The authors thank Mr Michael James Candlish for orthography and grammar correction. The authors also thank Ms Jianwen Yang for image collection.

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