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Amniotic membrane transplantation for porous sphere orbital implant exposure

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Abstract: Objective: This study is aimed at describing the clinical outcome of amniotic membrane transplantation for exposure of porous sphere implants. Methods: A retrospective review of consecutive cases of porous sphere orbital implant exposure was carried out. Eight cases were presented between May 2004 and Oct. 2006 (5 males, 3 females; mean age 44.5 years). Six had enucleation and two had evisceration. Exposure occurred in two primary and six secondary. Orbital implant diameter was 22 mm in seven cases and 20 mm in one case. Six patients are with hydroxyapatite and two with high-density porous polyethylene (Medpor) orbital implants. The mean time from implantation to exposure was 1.1 months (range 0.8~2 months). All patients required surgical intervention. Results: The time of follow-up ranged from 3.0 to 28.0 months (mean 16.5 months). Amniotic membrane grafting successfully closed the defect without re-exposure in all of these patients. The grafts were left bare with a mean time to conjunctiva of about 1 month (range 0.8~1.5 months). Conclusion: Exposed porous sphere implants were treated successfully with amniotic membrane graft in all of patients. The graft is easy to harvest. This technique is useful, dose not lead to prolonged socket inflammation and infection, and it is valuable application extensively.

Key words: Amniotic membrane transplantation, Orbital implants, Exposure
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INTRODUCTION

Porous spherical implants are in general used to replace volume after enucleation or evisceration, with the fitting of a prosthetic eye to give good aesthetic result (Danz, 1990; Shields *et al*., 1993; Karesh and Dresner, 1994; Fan and Robertson, 1995). These implants are biocompatible and become vascularized, preventing migration and extrusion. The most common complication of porous spherical implants is exposure caused by breakdown of the covering layers (0~35% incidence), which may lead to extrusion and infection (Buetiner and Bartley, 1992; Remulla *et al*., 1995; McNab, 1995; Oestreicher *et al*., 1997; van Acker and de Potter, 2001; Lee *et al*., 2000; Martin and Ghabrial, 1998). Various methods described to close the defect are not always satisfactory. In this retrospective study, we aimed to evaluate the use of human sterilized freeze-dried amniotic membrane (FD-AM) in managing the exposure of porous spherical implants.

MATERIALS AND METHODS

Consecutive adult patients with porous implant exposure presented to our Department of Eye Center between May 2004 and Oct. 2006 were identified from the clinic database. A retrospective case note review of these consecutive cases was carried out. Patient demographics, details of original and secondary surgical procedures, type of implants, timing of exposure and the prior procedure were recorded (Table 1).

Exposure was initially treated conservatively (topical antibiotics with levofloxacin, prosthetic manipulation as necessary). Surgical treatment was indicated if exposure persisted.

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Table 1 Case review of Medpor and hydroxyapatite sphere exposure

Case	Age (year)	Sex	Porous sphere orbital implant			Time from implantation to exposure (months)	Size of defect (mm)	Prior procedure
			Implant	Diameter (mm)	Type			
1	44	F	Secondary	22	H	1.0	4×7	−
2	36	F	Primary	20	H	0.8	5×8	−
3	52	F	Secondary	22	H	1.0	5×6	−
4	59	M	Secondary	22	M	1.5	8×8	−
5	52	M	Secondary	22	H	0.8	5×7	−
6	30	M	Secondary	22	H	0.8	5×9	−
7	40	M	Primary	22	M	2.0	6×6	Conjunctivoplasty
8	40	M	Secondary	22	H	0.8	4×6	Conjunctivoplasty

H: Hydroxyapatite orbital implants; M: High-density porous polyethylene (Medpor)

After retrobulbar anaesthesia, 360° conjunctival relieving incisions are made adjacent to the exposed area. Tenon's fasciae are closed when possible and sutured to its anterior surface. A pocket between the conjunctival defect area and Tenon's fascia is created into which the edge of the amniotic membrane is placed.

In this study, human sterilized FD-AM was obtained from Jiangxi Ruiji Bio-Engineering Technology Co., Ltd., China. Human amniotic membrane deprived of amniotic epithelial cells by incubation with EDTA was freeze dried, vacuum packed and sterilized with γ-irradiation. The membrane was rinsed three times in saline before use. After thawing, the amniotic membrane was removed from the filter paper and placed over the conjunctival defect with the basement membrane side up. The smooth basement membrane side of the amniotic membrane could be distinguished from the sticky sromal side. The amniotic membrane was trimmed to fit the entire conjuntival defect and then secured to the recessed conjunctival edge with a few interrupted or running 8-0 Vicryl sutures so that its margin was placed under the conjunctival margins to facilitate epithelial growth over the membrane. Care was taken to avoid trapping blood under the membrane. Postoperatively, a conformer and antibiotic ointment were placed within the fornices. A temporary suture tarsorrhaphy was placed at the completion of all the cases and opened to observe the fluorescein staining over the amniotic membrane once a week and removed eight weeks postoperatively.

All patients were treated with cefradine and dexamethasone by intravenous drip for one week and topical antibiotics was applied with levofloxacin four times a day for eight weeks.

RESULTS

All patients in this series had amniotic membrane grafting at an average of 3.8 months after exposure first occurred. Amniotic membrane transplantation (AMT) achieved successful repair of porous sphere (Medpor and hydroxyapatite) implants exposure in all eyes. Complete epithelialization was observed 0.8~1.5 months (mean time 1 month) on the first postoperation visit when no fluorescein staining showed in over the amniotic membrane, resulting in a non-inflamed appearance of the surgical site.

In two eyes (cases 4 and 7), non-pyogenic granuloma developed in the first 3 months after surgery and was managed with topical corticosteroid injection (case 4) or with surgical excision (case 7). There were no cases of either granuloma formation or granuloma removal giving rise to exposure.

The mean follow-up period after surgery was 16.5 months (range 3.0~28.0 months). Conjunctivas were closed over the amniotic membrane without re-exposure in all of the patients. No patients had implant migration or extrusion or required removal of the implant. None had a contracted socket, forniceal shortening, conjunctival scarring, or a combination of these. Patients wore either a vaulted artificial eye or a conformer in the postoperative period (Table 1).

DISCUSSION

We describe the use of amniotic membrane grafts in the management of porous sphere (Medpor and hydroxyapatite) implants. In this small case series of porous polyethylene spheres, amniotic membrane

was used successfully in eight patients who needed surgery, healing at an average of within one month.

Small areas of tissue (<3 mm) breakdown can heal spontaneously (Yoon *et al*., 1994). In this series, none healed spontaneously. A persistently exposed implant had to be removed before in our hospital because of the chronic infection and the culture showed staphylococcus aureus growth. So that in our experience, once the exposure of porous polyethylene implant occurs, early surgical intervention was advocated to prevent infection and speed up rehabilitation of the patient. We performed the operation 3.8 months after exposure first occurred when the implant had been integrated with the fibrovascular tissues of the orbit.

Human amniotic membrane is the innermost layer of the placenta and consists of a thick bastement membrance and an avascular stroma. It can be used as a substrate to replace damaged mucosal surfaces and has been used successfully for reconstructing corneal and conjunctival surfaces damaged by various ocular surface disorders. A variety of characteristics make cryopreservation of amniotic membrane ideally suited for use in ocular surface reconstruction. The amniotic membrane stromal matrix also suppresses the expression of certain inflammatory cytokines that originate from the ocular surface epithelia including interleukin-1α (IL-1α), IL-2β, IL-2, IL-8, interferon-γ, tumor necrosis factor-α, β fibroblast growth factor, and platelet-derived growth factor. The suppression of inflammation is a key element in the prevention of further fibrovascular proliferation and scar formation in the conjunctiva. amniotic membrane supports the normal phenotype of a non-goblet conjunctival epithelium with goblet cell differentiation in vivo. In this regard, it is superior to buccal or nasal mucous membrane grafts, whose epithelia are different from that of the conjunctiva (Solomon *et al*., 2003).

Human sterilized FD-AM we used is favoured for three reasons. Firstly, for clinical use, it is easy to obtain, transport, and preserve at room temperature. Secondly, FD-AM can be preserved in the dry state and completely sterilized by γ-irradiation to make it safer to be used. Furthermore, it retains most of the physical, biological, and morphologic characteristics of cryopreserved amniotic membrane (Nakamura *et al*., 2004).

Even if the inflammation of the cicatricial process can be fully suppressed and controlled, there will be advanced cases in which the success of AMT is limited. This is because amniotic membrane used as a substrate still relies on the migration, growth, and differentiation of the epithelial cells from the adjacent host conjunctiva. It should be noted that the reconstructed area can be very large as long as the underlying bed is not ischemic and the adjacent host conjunctiva remains normal.

A relative disadvantage of this technique is the requirement to install ring plastic conformer and perform a temporary tarsorrhaphy after operation for the sake of occupying a large space and minimizing upper eyelid movement and subsequent traction on the pedicle graft. Although amniotic membrane carried the risk of fornical shortening, eyelid retraction, and eyelid margin deformities (especially entropion of the upper eyelid), our patients experienced none of these complications.

Postoperative granuloma formation did not cause exposure, but was a secondary healing response. In another report, exposure occurred after the granulomatous inflammatory response was treated with intensive topical steroid and settled on discontinuation (Inkster *et al*., 1994; Sagoo and Olver, 2004). Both granulomatous response and tissue breakdown have been reported (Christmas *et al*., 1998).

It is difficult to identify risk factors from this small case series. We think it can be minimized by taking the following steps at the time of surgery: choose an appropriately sized implant; place the implant posteriorly to Tenon's capsule and suture the extraocular muscle tendons more anteriorly than their normal position to provide additional stability and to reduce tension on the Tenon's closure; when the incision is closed, the conjunctiva should be dissected free from the underlying Tenon's capsule and these two tissue layers should be meticulously stitched separately without any tension.

CONCLUSION

The use of human sterilized FD-AM enables successful repair of porous sphere polyethylene (Medpor) and hydroxyapatite implant exposure without leading to prolonged socket inflammation, infection, or extrusion, and should be considered

where conservative treatment is not curative, especially after previous attempts to cover the implant have failed.

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