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Sustained descemetocele management with Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) treatment

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ABSTRACT

Purpose: To report a case of a 67-year-old male who was successfully managed over a 7-year period for descemetocele secondary to ocular graft versus host disease (oGVHD) using Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) treatment.

Observations: We previously reported on a patient managed with a PROSE device for severe dry eyes secondary to oGVHD, who subsequently developed a central corneal descemetocele. The patient was deemed a poor surgical candidate due to limbal stem cell deficiency secondary to oGVHD. Therefore, we elected to closely monitor the descemetocele as the patient continued PROSE therapy. The patient's descemetocele has been managed successfully without perforation throughout a 7-year follow-up period with corrected distance visual acuity remaining stable at 20/50 in the affected eye.

Conclusions and importance: Descemetoceles are an uncommon complication of ocular graft versus host disease. This is the longest published report of a corneal descemetocele managed with PROSE. Our report suggests that in appropriate patients who are at high-risk for post-surgical complications, PROSE in conjunction with other medical management should be considered as an alternative to corneal transplantation.

1. Introduction

A corneal descemetocele occurs when the intact Descemet membrane becomes exposed.[1] Etiologies of descemetoceles include microbial keratitis, neurotrophic keratitis, dry eye disease, iatrogenic/traumatic etiologies, corneal dystrophies as well as systemic conditions with ocular manifestations.

Chronic graft versus host disease (GVHD) represents one such systemic entity whereby donor lymphocytes (predominately T cells) target host antigens following allogeneic hematopoietic stem cell transplantation. Ocular involvement has been reported to affect 60–90 % of GVHD cases.[2] Ocular GVHD (oGVHD) affects multiple structures including the lacrimal glands, meibomian glands, eyelids, and ocular surface leading to the development of keratoconjunctivitis sicca in 40–76 % of cases, as well as cicatrizing conjunctivitis and trichiasis, ectropion, entropion, and lagophthalmos.[2,3] This disruption to ocular surface integrity may eventually lead to the development of corneal ulcers with subsequent corneal thinning and descemetocele formation.[4]

Regardless of etiology, urgent intervention is warranted in all cases of descemetocele given the risk of corneal perforation. Treatment options for descemetocele are numerous, often depending on the size and location of the descemetocele. Conventional management of descemetoceles includes prevention of descemetocele associated corneal perforation with protective eyewear as well as bandage contact lenses, adhesive application, amniotic membrane transplantation (AMT), conjunctival flaps, and keratoplasty.[5,6] Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE, BostonSight, Needham, MA) devices represent a type of scleral contact lenses which have shown benefit in the management of various ocular surface diseases including oGVHD.[7,8] PROSE devices vault over the corneal surface to rest on the sclera/conjunctiva and are comprised of a gas-permeable polymer, with the capability for custom modifications and additional venting channels on the posterior surface, which help to facilitate increased tear exchange during blinking.[9] Their design facilitates constant lubrication and oxygenation of the ocular surface thereby reducing inflammation while providing epithelial protection.

We previously reported a case where a patient with descemetocele secondary to oGVHD was managed over the course of one year with PROSE therapy.[10] Since our initial publication, a subsequent report also demonstrated the successful management of a descemetocele over a

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one-year period with scleral contact lenses. In that report, the patient developed a descemetocele following surgical repair of a ruptured arteriovenous malformation complicated by cranial nerve V and VII palsy, causing subsequent neurotrophic and exposure keratopathy.[11] Our current report presents a 7-year update to our patient's clinical course, whereby we demonstrate sustained management of the descemetocele with PROSE therapy.

2. Case

As we previously reported, a 56-year-old male with GVHD secondary to hematopoietic stem cell transplantation for mantle cell lymphoma presented to USC Roski Eye Institute with severe dry eyes. His initial uncorrected visual acuity was 20/60 OD and 20/70 OS, and his initial Ocular Surface Disease Index (OSDI) score was 81.25. Anterior segment examination was significant for 4+ punctate epithelial erosions (PEEs) with conjunctival staining and tear film mucus OS > OD. PROSE devices were designed to vault the cornea and limbus; toric peripheral curves with a diameter of 18.0 mm were used to best contour the scleral shape. Oprificon A material with Dk 85 (Boston Equalens II, Bausch + Lomb, Wilmington, MA) was used. The lenses subsequently improved the patient's visual acuity to 20/25 OD and 20/20 OS.

At the initiation of PROSE treatment, the patient was advised that he could wear his PROSE devices for an average of 8–14 hours a day, with midday breaks as needed to clean or refresh the lenses. He was instructed against napping or sleeping in the lenses, as this could lead to complications including inflammation or microbial keratitis. Detailed guidelines were provided on proper lens handling, cleaning, storage, and maintenance protocols. Only non-preserved sterile saline could be used to rinse and fill the PROSE lens reservoir prior to wear. He was also advised to apply preservative free artificial tears as needed over his PROSE devices during the day to improve comfort and vision quality.

Following 2 months of PROSE wear, corneal staining improved to 1+ PEE and the OSDI score was reduced to 5, marking a 94 % improvement in symptoms. Despite compliance with PROSE usage, the patient developed a 1-mm central infectious corneal ulceration OD four years after initial presentation. Daily PROSE lens wear was reinitiated 2 days after initial ulcer diagnosis to allow for better support of the ocular surface, as well as improved comfort and vision. The patient was instructed to sterilize and clean the lens frequently during the day to minimize inflammatory and infectious debris on the ocular surface; overnight wear was not permitted. Topical moxifloxacin 0.5 % was continued and instilled without lens wear, and within the PROSE lens reservoir during active infection. The patient was monitored closely over the course of the next month until the infection resolved. Three months after initial ulcer diagnosis, the cornea demonstrated approximately 95 % focal thinning based on slit-lamp bio microscopy (Fig. 1A and B), with thinning confirmed on anterior segment optical coherence tomography (AS-OCT), with progression to a descemetocele.

The patient continued daily PROSE usage with the descemetocele remaining stable at 1-year follow-up, measuring 0.75 × 1.5mm (Fig. 1 C, D). AS-OCT imaging of the descemetocele at 1 year after diagnosis showed corneal re-epithelialization with a maximal thinning of 52μm compared with the unaffected surrounding corneal tissue at 595 μm (Fig. 2A), which remained stable on AS-OCT imaging during the 2-year follow-up (Fig. 2B). In conjunction with recommendations from hematology, the patient was initiated on oral tacrolimus for further systemic management of his oGVHD. At the 3-year follow-up, the descemetocele had enlarged to 2.5 × 3.0mm (Fig. 1 E, F). The decision was made to taper tacrolimus and initiate treatment with 60 mg of oral prednisone, gradually tapered over the subsequent 3-months, which temporarily stabilized the descemetocele at 2.7 × 5.2mm. However, progressive enlargement recurred the following year prompting initiating of plasma photopheresis over 5-sessions coupled with a 6-month course of oral ruxolitinib. The descemetocele's size remained stable at 3.0 × 6.3mm during the patient's 5-year follow-up (Fig. 1G and H), with AS-OCT also demonstrating descemetocele stability (Fig. 2C). Stability was again confirmed during the most recent 7-year post-descemetocele formation follow-up (Fig. 1I and J).

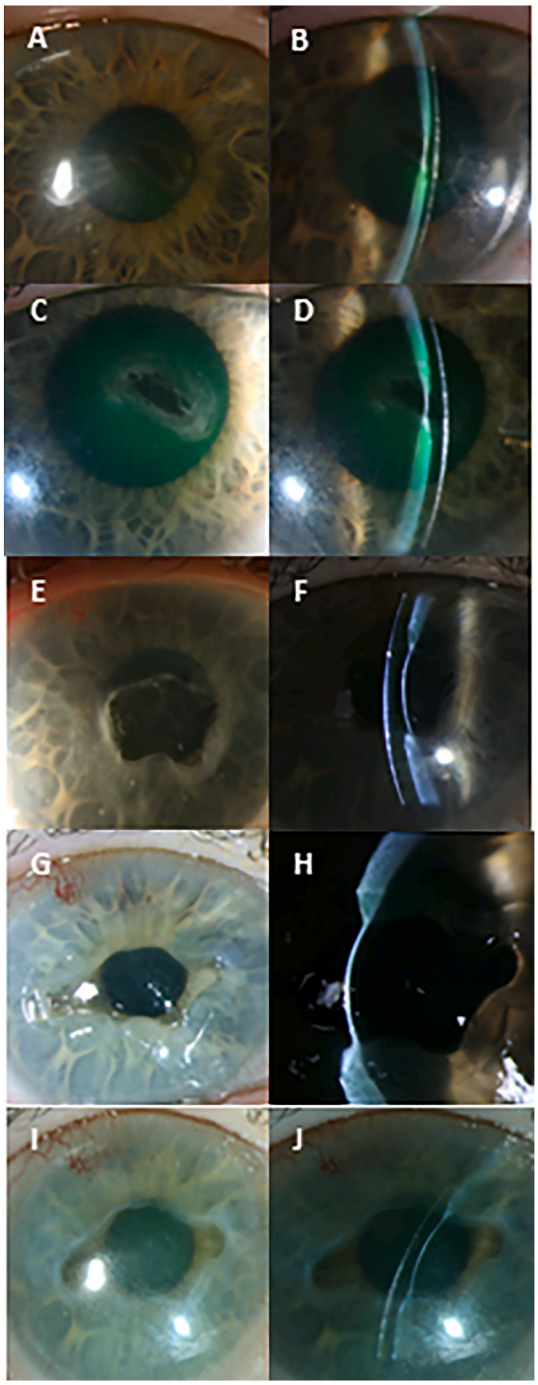

Fig. 1. Slit-lamp photographs of the central descemetocele under a PROSE device in the right eye at 3-months (A and B), 1-year (C and D), 3-years (E and F), 5-years (G and H), and 7-years (I and J).

Of note, the patient's overall health remained stable during the period of descemetocele development and evolution. Aside from some nail dystrophy, the patient maintained good mobility and exercised routinely. Given the severe corneal thinning, he employed protective eyewear during exercise for further mechanical protection against traumatic corneal rupture. Additionally, the patient had been successfully tapered off all immunosuppression at time of final follow-up. The patient's only topical medication remained preservative free artificial

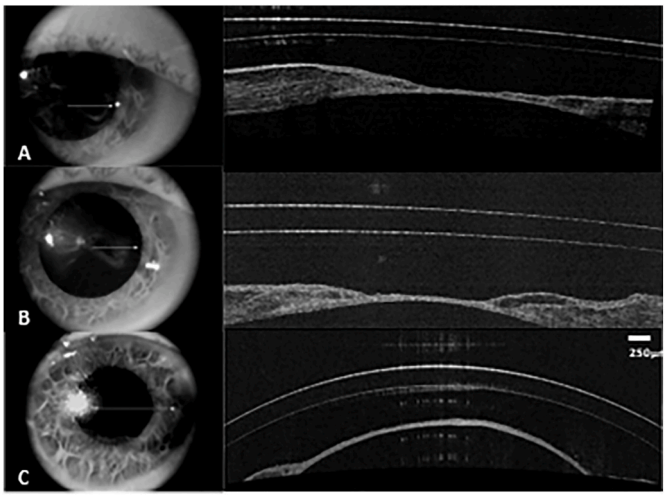

Fig. 2. Anterior segment OCT images showing the descemetocele under a PROSE device at 1-year (A), 2-year (B), and 5-year (C) follow-up demonstrating progressive enlargement of the descemetocele. Corneal thinning at 1-year was measured to be approximately 52μm which remained stable throughout the 5-year follow-up.

tears. Regarding the patient's subjective dry eye symptoms, the OSDI score further improved to 2 during the most recent 7-year follow-up, marking a 98 % improvement in symptoms compared to his earliest score before PROSE therapy.

During the years of descemetocele development and subsequent enlargement, PROSE scleral lens daily wear was maintained in both eyes. This allowed for continued relief to the patient's dry eyes, improved vision, and protection of the ocular surface. However, lens breaks were recommended more frequently in the affected right eye, to allow for adequate oxygenation to the cornea, instillation of necessary topical medications needed at the time, and refreshing of the ocular surface and lens. Lens breaks were taken about 2–4 times a day, and for about 15–30 minutes at a time. The patient could not tolerate longer durations without PROSE lens wear due to his severe ocular surface disease.

Because of the ulcer and resulting descemetocele's central location, corrected distance visual acuity (CDVA)with PROSE declined to 20/200 OD 4 days after initial ulcer presentation and improved to 20/50 1 year later, where it has remained until the most recent 7-year follow-up. CDVA with PROSE wear is 20/25 OS. Of note, the patient also has mild nuclear sclerosis and posterior subcapsular cataract somewhat limiting visual potential. PROSE design and prescription were updated slightly approximately every 1–2 years to optimize vision and fit over the 7-year follow-up period, and most recently to account for the slight myopic shift due to cataract progression.

3. Discussion

Descemetocele and corneal perforation represent rare complications of oGVHD, with perforations estimated to occur in 1–4% of oGVHD cases.[12–15] Surgical management of descemetocele and perforation in oGVHD presents certain challenges given that the accompanying keratoconjunctivitis sicca and limbal stem cell deficiency as well as the immunocompromised host status may predispose to delayed wound healing and higher rates of post-surgical complications. These challenges are highlighted in a case report by *Mohammadpour* et al. which featured an oGVHD patient who developed recurrent corneal perforations despite multiple medical and surgical interventions, including cyanoacrylate glue, AMT, and ultimately, penetrating keratoplasty (PKP).[16]

Another retrospective study by *Zhang* et al. examined 14 patients who developed corneal perforation secondary to oGVHD and found that corneal perforation occurred on average 27.5 months after the diagnosis of oGVHD.[17] The authors report that soft bandage contact lenses or scleral lenses were employed in 7 of their patients. However, it is unclear if scleral lenses were employed prior to or following the corneal perforation and what proportion of these 7 patients were treated with scleral lenses specifically. Of their patients, 8 underwent PKP with 5 out of 8 patients requiring multiple PKPs throughout the follow-up interval. Final CDVA ranged from 20/60 to NLP in eyes that underwent PKP. These findings are consistent with *Xu* et al.*'s* report of 9 eyes from 7 patients with oGVHD which found that corneal perforation occurred on average 4 months after the diagnosis of oGVHD.[14] In their cohort, 5 eyes underwent PKP, 1 underwent conjunctival flap closure, and 3 underwent both procedures. Despite surgical intervention, final visual acuity remained poor, with most of their patients having a final CDVA of 20/100 or worse. It is unclear if scleral lenses were employed for any of these patients. Yet another case series by *Inagaki* et al. examined the clinical course of 4 oGVHD patients with corneal perforation, with 3 of these patients eventually undergoing deep lamellar anterior keratoplasty (DALK).[18] In this study, corneal perforation occurred on average 17.7 months after diagnosis of oGVHD and between 1 and 5 weeks after onset of corneal ulcer. The patients who underwent DALK ultimately had CDVAs of 20/200 or worse. None of the patients in this study were treated with scleral lenses.

Collectively, these reports suggest progression to corneal perforation can occur rapidly after diagnosis of oGVHD with visual acuity remaining limited even after surgical intervention. Theoretically, the use of scleral lenses earlier in the disease course of patients who manifest such severe ocular surface disease may provide mechanical protection to severely thinned corneas from the eyelids and external environment, and possibly prevent resulting corneal perforations and the need for surgery. It is also feasible that the oxygenation and constant lubrication provided by fluid filled reservoirs of these lenses could also play a role in preventing corneal desiccation, progressive epithelial breakdown, thinning, and ulceration.[19]

While implementation of scleral lens therapy has already proven to be effective in rapidly minimizing ocular symptoms in patients with oGVHD, there is a paucity of literature regarding their use in managing descemetoceles.[20,21] A growing body of literature describes the use of scleral lenses in severe ocular surface pathology including persistent epithelial defects, neurotrophic and exposure keratopathy, as well as in severe corneal ectasias.[9,22–24] Corneal ectasias represent a leading indication for scleral lens use and, like descemetoceles, are also characterized by corneal thinning.[25] Emerging research suggests that scleral lenses may improve visual outcomes and reduce the likelihood that patients with corneal ectasias will require transplantation, with some research suggesting that scleral lens therapy may serve as an alternative to surgical intervention in select cases.[26,27] One study by *DeLoss* et al. compared outcomes of PROSE treatment with keratoplasty for advanced corneal ectasias and found that mean visual acuity, as well as the speed of visual recovery, was significantly better in the PROSE cohort compared with keratoplasty.[27]

Our patient who developed oGVHD 10-year ago and corneal ulcer 7-years ago has been successfully managed with PROSE therapy without corneal perforation or surgery while maintaining a CDVA of 20/50. Indeed, PROSE therapy remains an attractive candidate for managing oGVHD given its potential for both visual rehabilitation and managing the compromised ocular surface. Scleral lenses are generally well tolerated. Though complication rates vary widely amongst publications, most are mild and can be managed with patient education, lens refitting, or adjusted wear time.[25,28]

PROSE therapy appears to be particularly well tolerated with only a 2.5 % complication rate leading to discontinuation of wear reported in one longitudinal 5-year study.[29] This same study found that patients with irregular corneas or ocular surface disease secondary to oGVHD were more likely to comply with long-term PROSE wear compared with

other indications. Of note, our patient developed corneal ulceration and subsequent descemetocele while employing PROSE therapy. It is possible that the use of PROSE therapy, with the associated digital manipulation from frequent lens insertion and removal, contributed to the development of the ulcer. However, the patient was already at risk of developing an infection given his compromised ocular surface, so it is difficult to ascertain to what degree PROSE therapy contributed to the ulcer.

It is important to note that microbial keratitis (MK) is a serious and potentially sight-threatening complication of scleral lens wear.[30,31] The exact prevalence of MK associated with scleral lens wear, however, is not clear. Two large retrospective reviews of scleral lens use have estimated the rate of microbial keratitis at 0.5–1.6 %.[9,22] Of note, microbial keratitis does not necessarily dictate the long-term cessation of scleral lens use.[9] Regardless, some practitioners have advocated for prophylactic antibiotic eyedrop use with scleral lenses, particularly in the context of extended wear for the treatment of persistent corneal epithelial defects.[9,30,32] In one retrospective study where 4 out of 22 eyes developed microbial keratitis, the remaining 18 eyes did not develop ulceration when prophylactic moxifloxacin drops were applied to the scleral lens fluid reservoir.[9] This finding was mirrored in a study by *Lim* et al. where no cases of microbial keratitis developed with adjunctive moxifloxacin in the scleral lens reservoir.[33] Ultimately, treatment with scleral lenses must be weighed with the risks and benefits associated with other treatment modalities including surgery and should be considered in patients who are poor surgical candidates.[29] In the study by *DeLoss* et al., there were no complications associated with the PROSE cohort at 1-year whereas the patients treated with keratoplasty had a combined 16.3 % intraoperative and post-operative complication rate at 1-year including lens expulsion, cataractogenesis, graft rejection, elevated intraocular pressure, and suture abscess with corneal perforation. Regardless, patients' ability to comply with the proper instructions for scleral lens wear and care as well as the proximity and availability of providers able to fit scleral lenses represent significant limiting factors for their wider implementation.[27]

4. Conclusion

We have presented a 7-year update to our initial report of a corneal descemetocele secondary in a patient with oGVHD successfully managed with PROSE therapy. Currently, only one other report by *Gelles* et al. exists of long-term non-surgical descemetocele management.[11] Their patient was also deemed a poor surgical candidate and demonstrated descemetocele stability, as well as improvement in visual acuity from count fingers to 20/100 over the course of their 1-year follow-up following implementation of scleral lens therapy. Collectively, our cases suggest that scleral lenses may improve quality of life, partially restore visual acuity, and help defer keratoplasty in appropriate patients with severe ocular surface pathology. Ultimately, further studies are needed to elucidate the role of scleral lenses in descemetocele management and other conditions characterized by severe and progressive corneal thinning.

Patient consent

Consent to publish the case report was obtained. This report does not contain any personal information that could result in patient identification.

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CRediT authorship contribution statement

Alexander M. Tseng: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Martin Heur:** Writing – review & editing, Resources, Funding acquisition, Formal analysis, Data curation. **Gloria B. Chiu:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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