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Case report

Transient corneal epithelial bullae associated with large diameter scleral lens wear: A case series

Veronica L. Isozaki*, Gloria B. Chiu

USC Roski Eye Institute, University of Southern California, 1450 San Pablo Street, 4th Floor, Los Angeles, CA 90033, USA

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ABSTRACT

With the increased fitting of scleral lenses by eye care practitioners, complications with lens wear need to be considered. Several prior studies have addressed complications specific to scleral lens wear and the incidence of hypoxia with extended wear, but few report the presence of epithelial bullae. This case series investigates three patients with differing ocular surface diseases, yet all developed transient epithelial bullae with concurrent large diameter scleral lens wear. These bullae appear to form due to weakened connections in the corneal epithelium at the level of basement membrane and Bowman's layer and flatten within minutes of lens removal. These bullae need to be further studied, as they can increase the patient's risk of epithelial defects, infections, and other complications in already compromised corneas.

1. Introduction

A scleral lens is defined as a lens that rests entirely on the sclera and conjunctiva regardless of the diameter of the lens [1]. Because this type of specialty contact lens completely vaults the cornea and limbus, it can provide significantly improved vision compared to glasses, as well as promote good ocular health in an otherwise diseased or damaged cornea. The use of scleral lenses was first noted in the 1880s as a ground glass shell, and since then scleral lenses have evolved in size, shape, materials, and fitting practice [2]. With the development of newer rigid gas permeable materials, they have become quite popular for the treatment of a variety of corneal conditions, including keratoconus, post-surgical ectasia, irregular corneas, and ocular surface disease. However, as with all other contact lens modalities, complications can arise with scleral lens wear.

The existing literature addresses several complications specific to scleral lens wear, such as lens seal-off, mid-day fogging, limbal bearing, and conjunctival prolapse or hooding [2–4]. Due to their large diameter and heavy weight on the eye, scleral lenses are known to settle into the conjunctiva even after only a few hours of wear [3]. The lens can then suction onto the eye and "seal-off", resulting in reduced tear exchange under the lens and stagnation of fluid between the lens and the cornea. This can expose the cornea, which may already be compromised, to toxic metabolic waste for prolonged periods of time [2]. In addition, lens seal-off can contribute to mid-day fogging due to the retained debris under the lens within the fluid chamber, causing occasional blur that may require patients to refill their scleral lens with fresh solution mid-day, or use high viscosity, preservative-free artificial tears to fill their lens. Limbal bearing must also be closely managed, as the limbus is an area for renewal and proliferation of epithelial cells. While scleral lenses can be used to treat limbal stem cell deficiency (LSCD) [5], an ill-fitting scleral lens can potentially cause it as well. Lastly, conjunctival prolapse, or hooding, occurs due to the negative pressure beneath the scleral lens pulling the loose peripheral conjunctival tissue over the peripheral cornea [2,4].

Complications from infection can arise with any type of contact lens wear, but in the case of scleral lenses, these complications must be uniquely addressed. While scleral lenses are an excellent treatment option for patients with ocular surface disease, these patients can be at risk for microbial keratitis, as the already compromised epithelium can be an entry site for microorganisms [6]. These patients are also typically on oral and/or topical steroids to manage their underlying condition, which further reduces their immune protection against infection [2,7]. However, infection with scleral lens wear is rarely reported in the literature [6–8], and the low incidence of microbial keratitis can be attributed to the fact that scleral lenses are worn on a daily basis, compared to extended wear with soft contact lenses. It is therefore vital to closely monitor these patients, and encourage daily wear with adequate contact lens hygiene.

The complication most interesting to this study is that of hypoxia. Several studies have investigated the effects of combined scleral lens thickness and fluid chamber vault on hypoxia leading to corneal edema. Michaud et al. determined that in order to meet the standards developed by Holden and Mertz [9] to provide enough oxygen to the cornea

* Corresponding author.
E-mail addresses: Veronica.Isozaki@med.usc.edu (V.L. Isozaki), Gloria.Chiu@med.usc.edu (G.B. Chiu).

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and avoid central corneal edema, a scleral lens must be no greater than 250 µm thick, manufactured in the highest *Dk* material (> 150) available, and fit so that the fluid chamber vault is no more than 200 µm [10]. Jaynes et al. also concluded that scleral lenses should be manufactured from the highest reasonable *Dk* materials and fit without excessive clearance [11]. Compãn et al. found similar results, in which the scleral lens must be no more than 200 µm thick, have a *Dk* of at least 125, and vault the cornea no greater than 150 µm [12]. Then in a follow-up study, Compãn et al., using an updated model to measure corneal oxygen supply, found similar results to Michaud and Jaynes that the majority of current scleral lenses available produce some levels of corneal hypoxia regardless of variance in vault or lens thickness. However, they did find that varying the fluid chamber vault had a greater effect on corneal oxygen supply than changing contact lens materials with higher *Dk* [13].

Unfortunately, all of these studies acknowledged the difficulty of following these recommendations given current materials and lens designs available. In addition, they all acknowledged that there is little reported in the literature regarding clinically significant scleral lens induced cornea edema. This may be due to a combination of insufficient clinical techniques to quantify these adverse effects, a small and very individualized scleral lens-wearing population, and the fact that corneas fit with scleral lenses are typically compromised. These authors agree there may be low-grade chronic corneal hypoxia that needs to be further evaluated, as well as measured against the benefits of having functional vision with scleral lens wear [2]. Therefore, it is still undetermined if clinically significant hypoxia is actually induced by scleral lens wear or due to other factors, and further investigation needs to be completed.

2. Theory

Corneal microcyst presence with contact lens wear is prevalently documented in the literature [14–17], but not much is reported regarding contact lens associated epithelial bullae. Microcysts are defined as “small (15–50 µm), translucent, irregular-shaped epithelial inclusions…scattered across the cornea” [14]. They have a slow onset, usually taking two months of contact lens wear before presenting in significant numbers, and take three months to clear when contact lens wear is discontinued [14,15].

Epithelial bullae are defined as “transparent, flattened, irregularly shaped, cobblestone-like formations that vary in size and are fairly large (40 µm or larger)” [16]. They also have an oval shape with indistinct borders, coalesce into clusters, and tend to be associated with chronic corneal edema, which concurs with these prior studies of subclinical hypoxia due to scleral contact lens wear. Epithelial vacuoles are also transparent and round, but are small (20–50 µm) formations with distinct borders that typically present toward the mid-periphery of the cornea and can be observed after one week of contact lens wear [16]. In the following cases, the corneal presentations are large, irregular shaped pockets with distinct borders that present after extended hours or longer periods of scleral lens wear, suggesting they are most closely related to epithelial bullae rather than vacuoles or microcysts. The transient nature of these proposed epithelial bullae is intriguing, and this case series aims to investigate this finding to better understand scleral lens interactions with the ocular surface and any complications that may arise with long-term wear.

3. Cases

The following cases describe the presentation of transient epithelial bullae in three patients with severe ocular surface disease and concurrent large diameter scleral lens wear.

3.1. Case 1

A 37-year old Assyrian male presented with complaints of severe ocular burning, pain, and light sensitivity. He had large bilateral corneal epithelial defects, which had been persistent for three weeks. Prior ocular therapies included topical steroids, topical antibiotics, copious artificial tears and ointments, cyclosporine 0.05%, soft bandage contact lenses, punctal plugs, humidifiers, and goggles. His medical history was significant for acute myelogenous leukemia (AML), a bone marrow transplantation, and subsequent development of chronic graft *versus* host disease (GVHD). The GVHD ultimately affected his muscles, skin, mouth, and eyes. He had been referred by his ophthalmologist for Prosthetic replacement of the ocular surface ecosystem (PROSE) treatment (BostonSight, Needham, MA), which utilizes custom scleral devices to restore visual function, support healing, and reduce symptoms in patients with diseased corneas.

During his initial consultation, the patient was determined to be a good candidate for PROSE treatment, with a short term goal of healing the persistent epithelial defects and long term goals of improved comfort, vision, and protecting the ocular surface [18–20].

Incoming bandage contact lens corrected visual acuities were 20/50+ OD, with no improvement on pinhole, and 20/400 OS, with pinhole improvement to 20/100. PROSE lens corrected visual acuities were 20/25-2 OD and 20/100 OS. The patient also reported improved comfort compared to bandage contact lenses and reduced ocular discomfort in both eyes. Custom devices with an 18.0 mm diameter and toric peripheral curves were ordered and arrived the following week.

In an effort to help expedite healing of the epithelial defects, the patient was instructed to wear his PROSE lenses on an extended wear basis. After one complete day of continuous wear, the patient returned to clinic for evaluation. During this visit, slit lamp examination revealed multiple new areas of epithelial bullae, extending temporally from 6:00 to 12:00 in the right eye. Fig. 1 shows a color slit lamp photograph of the epithelial bullae in the right eye just a few minutes after scleral lens removal. The bullae were initially more pronounced with the scleral lens in place. No limbal bullae were appreciated in the left eye.

Given this issue of limbal swelling and epithelial bullae in the right eye, PROSE extended wear was discontinued. This complication was made known to his referring ophthalmologist, who saw him for follow up the next day. New soft bandage contact lenses were placed in each eye, and the patient was instructed to continue polymixin B, neomycin, bacitracin 1 drop QID OU, along with artificial tears as needed.

After two more months under the care of his ophthalmologist, the bilateral epithelial defects had not fully healed. During this period, the patient continued topical medications and wore bandage contact lenses. In addition, the patient’s hematologist was contacted and his systemic

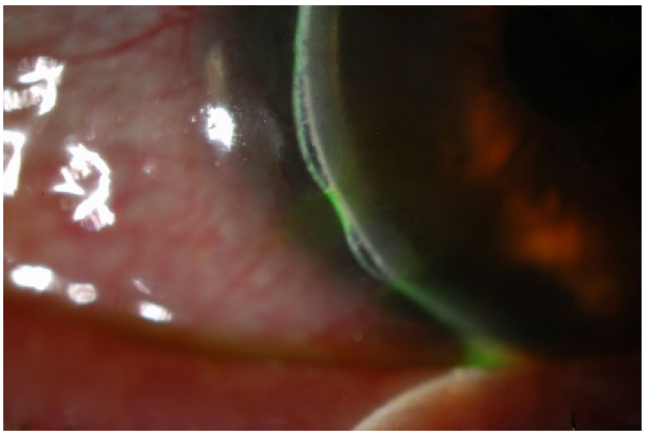

Fig. 1. Case 1. Color slit lamp photograph of epithelial bullae near inferior temporal limbus OD, a few minutes after PROSE lens removal. Images reprinted with permission from Chiu et al. [20].