Contact Lens & Anterior Eye 36 (2013) 159–163

Contents lists available at SciVerse ScienceDirect

Contact Lens & Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Patient ocular conditions and clinical outcomes using a PROSE scleral device

Ryan Dimit[a,*], Anisa Gire[a,b], Stephen C. Pflugfelder[a], Jan P.G. Bergmanson[c]

[a] Alkek Eye Center, Baylor College of Medicine, Houston, TX, USA
[b] Johns Hopkins University, Wilmer Eye Institute, USA
[c] Texas Eye Research and Technology Center, University of Houston College of Optometry, Houston, TX, USA

ARTICLE INFO

Article history:
Received 21 October 2011
Received in revised form 11 February 2013
Accepted 14 February 2013

Keywords:
Scleral contact lenses
Keratoconus
Dry eye
Visual function
Questionnaire

ABSTRACT

Purpose: To determine the type and distribution of ocular conditions cared for in a clinic dedicated to scleral devices and to report the clinical outcomes afforded by this approach.
Methods: Fifty-one charts of patients fitted unilaterally or bilaterally with a scleral device (Prosthetic Replacement of the Ocular Surface Ecosystem – PROSE) in a two year period were retrospectively reviewed. Patient demographics, ocular diagnoses, associated systemic conditions, best corrected visual acuity (BCVA) before and after fitting, Visual Function Questionnaire score (VFQ-25), and ocular surface disease index (OSDI) score were collected.
Results: All 51 patients were successfully wearing the PROSE device for a period of anywhere from weeks to years. The most common reasons for fitting were to relieve symptoms of moderate to severe dry eye syndrome ("DES", $n = 25$), management of refractive problems ("refractive", $n = 23$) with keratoconus being the most common ($n = 14$), and to manage other anomalies ("other", $n = 3$). Best corrected visual acuity (logMAR) improved with the wearing of the PROSE device for both the DES (17 letters) and the refractive group (10 letters), but not the "other" group. No serious complications were recorded for any of the patients.
Conclusions: The PROSE device is a useful option not only for the management of ocular surface disease and optical imperfections, but also for other ophthalmic conditions. Moderate to severe dry eye was the most common anomaly managed, followed by eyes with irregular corneal astigmatism. DES and refractive patients experienced improvement in visual acuity with wearing of the PROSE device.

1. Introduction

1.1. Scleral lens history

The first reported correction of ocular optical imperfections and treatment of ocular conditions using a scleral contact lens or shell date back to the late 1880s. Friedrich A. Müller and Albert C. Müller were the first to fit a scleral shell in 1887, when they created a glass shell for a patient who had his eye lids removed due to cancer [1]. Adolf Eugen Fick described the design and fitting of a blown glass scleral shell used to correct for irregular corneal astigmatism in 1888, becoming the first to publish an article in a medical journal on scleral shells [2]. Also in 1888, Eugène Kalt created a scleral shell for keratoconus [3]. In 1889, August Müller reported the first use of a scleral contact lens in the correction of his own high myopia [4].

Decades later, in 1923, a US patent (1,457,804) was granted to Albert Wigand as assignor for the firm of Carl Zeiss for a plastic scleral lens made of cellon or celluloid, but the company later abandoned these lenses. Scleral contact lenses of the late 1930s, made either partly [5] or totally from polymethylmethacrylate [6–8], had the advantages of significantly reduced fragility and easier modification of the back scleral zone (in order to optimize lens fit).

The introduction in the 1940s of the technique of fitting scleral lenses with minimum clearance of the corneal apex together with tear circulation, promoted either by fenestration at the edge of the optic zone [9] or by channels in the back scleral zone [10,11], allowed all-day wear to become the rule rather than the exception.

Prior to the advent of scleral lenses made of gas-permeable materials in 1983 it was difficult to fit scleral lenses successfully due to complications arising from corneal hypoxia [12]. However, the arrival of the gas-permeable lens material created an opportunity to develop a scleral lens that had acceptable physiological performance.

* Corresponding author at: Alkek Eye Center, Baylor College of Medicine, 1977 Butler Blvd., Houston, TX 77030, USA. Tel.: +1 713 798 3678; fax: +1 713 798 4489.
E-mail address: dimit@bcm.edu (R. Dimit).

1367-0484/$ – see front matter
http://dx.doi.org/10.1016/j.clae.2013.02.004

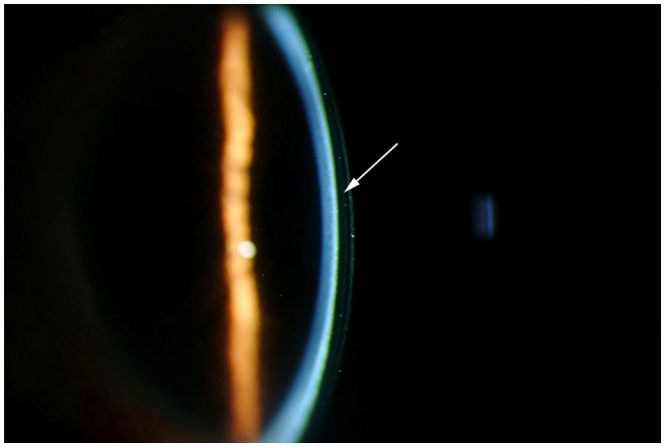

Fig. 1. Adequate central vault (arrow) of the PROSE lens.

1.2. Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) treatment

Today, a specific scleral lens design is used in the Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) treatment and because of its beneficial medical advantages the manufacturer has elected to call the PROSE a device rather than a contact lens. The acronym PROSE is used in conjunction with the words device and treatment, where the PROSE device is the specific design that is customized to each individual eye to deliver the PROSE treatment effect. PROSE devices have been reported to be effective and safe in managing a variety of conditions including chronic graft-versus-host disease, Steven–Johnson Syndrome, debilitating ocular surface disease, and following laser in situ keratomileusis surgery [13–16].

1.3. Overview of PROSE devices

PROSE devices are made of fluorosilicone/acrylate polymers, either oprifocon A or hexafocon B, having a Dk/t of 85 or 127×10^{-11} cm^2 mL O_2/s mL mmHg [ISO/Fatt] respectively. The diameter of the device can be made between 15 and 24 mm. In 1994 the US Food and Drug Administration (FDA) approved PROSE (scleral devices) for the treatment of corneal disorders. The PROSE device consists of an optic zone, a transition zone and a scleral zone [13]. The device is designed using spline functions, which create seamless junctions in the device between the optic zone and the scleral zone. The splines allow modification of the corneal vault (sagittal height) or distance between cornea and back surface of the optic zone (Fig. 1) independent of the base curve radius. This advanced control over device design allows for a complete customization for each patient's eye. Channels in the back surface of the scleral zone radiate tangentially from the center. During blinks these channels create a pumping mechanism to allow tear exchange underneath the device.

A trial set and a slit lamp biomicroscope are used to evaluate the fit of a PROSE device on the eye. The device is carefully inserted after it has been filled with unpreserved physiological saline to provide a bubble-free reservoir that acts as a liquid bandage while masking any corneal surface irregularities (Fig. 2). The optimal fit allows the device to rest on the sclera without causing compression of the conjunctival blood vessels while vaulting the entire cornea (Fig. 3). The device is fit to barely clear the steepest point of the cornea and give a uniform thickness of the fluid reservoir. If further modification of the device is needed, it is done during the ordering process with the help of a computer aided design program. Excessive compression of the conjunctiva over the sclera by the scleral zone is avoided to prevent blocking of the scleral zone channels that allow fluid ventilation and, thus, increase the comfort of the device. Excessive compression causes a feeling of pressure and an impression into the conjunctiva circumlimbally, noticeable upon device removal. The final device is ordered from and manufactured by the Boston Foundation for Sight (Needham, MA). The patient cares for the device using three different solutions. Non-preserved saline is used to rinse and fill the bowl of the device before insertion. Lobob Optimum Cleaner (Lobob Laboratories, Inc., San Jose, CA) is used

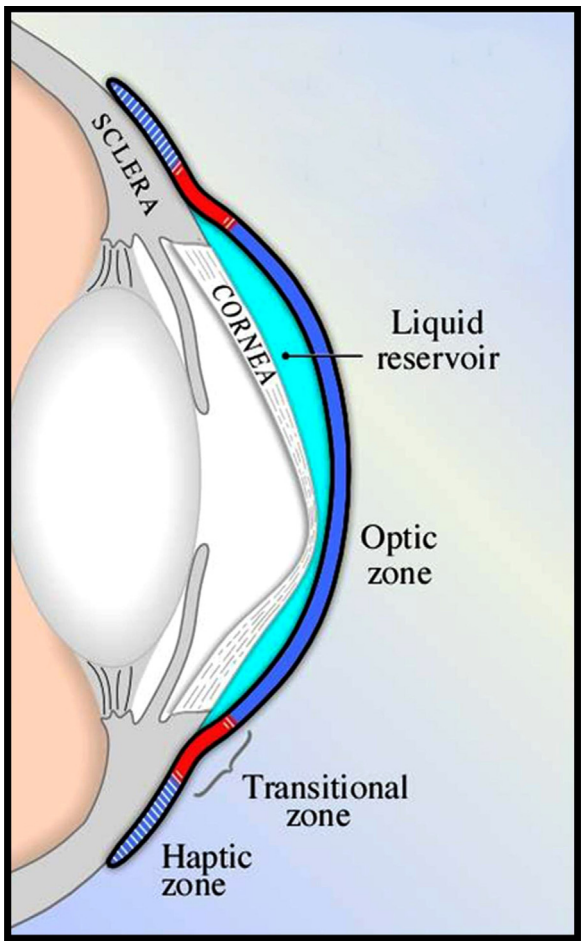

Fig. 2. Schematic diagram depicting overall PROSE lens design and fitting approach. Photo courtesy of Boston foundation for sight.

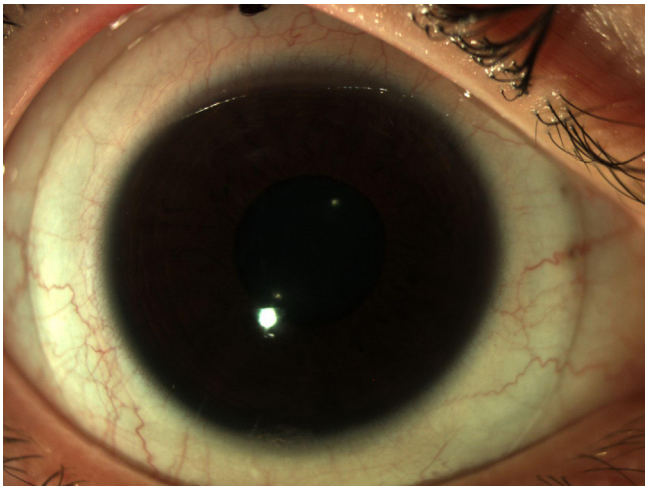

Fig. 3. A well centered PROSE lens.