

Update on scleral lenses

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Purpose of review

Scleral rigid gas-permeable lenses play an important and underappreciated role in the treatment of corneal disease. This review provides an update on scleral rigid gas-permeable lenses for the visual rehabilitation of ectasia and irregular astigmatism, and an update on scleral rigid gas-permeable lenses in the therapy of ocular surface disease.

Recent findings

Several series and one case report present advances in the treatment of ocular surface disease with scleral rigid gas-permeable lenses. In addition, there are two reports describing one center's consecutive case experience using modern scleral lens design, predominantly in patients with ectasia and postkeratoplasty astigmatism. Finally, a comprehensive article reviewing the history and principles behind current scleral rigid gas-permeable lenses, with particular attention to the use of scleral rigid gas-permeable lenses in the management of ocular surface disorders was published.

Summary

Clinicians who treat patients with ocular surface disease should be aware of scleral rigid gas-permeable lenses as a therapeutic option for their patients. Advances in lens design make scleral rigid gas-permeable lenses a practical option for an increasing number and variety of patients with corneal disease.

Keywords

ectasia, irregular astigmatism, ocular surface disease, scleral contact lens, scleral lens

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Introduction

Scleral rigid gas-permeable (RGP) lenses play an important and underappreciated role in the treatment of corneal disease. In the past year there have been several publications on scleral RGP lenses that serve to advance understanding of this role, particularly with respect to the treatment of ocular surface disease.

History of scleral lenses and principles of design

The first contact lenses reported in the medical literature were scleral lenses described in a report by Adolf Eugen Fick in 1888 [1]. In an excellent review of the history of contact lenses, Pearson [2•] reports Karl Otto Himmler as manufacturer of the first contact lens. Pearson describes lenses reported in 1888, 1888, and 1889, by Fick, Kalt, and Muller, respectively, all of which were of diameters ranging from 15 to 22 mm. Those interested in the history and evolution of current contact lens design and manufacture are encouraged to read this paper on the first reports of contact lenses, all of which were scleral in size. Hindsight reveals that these lenses failed because of inadequate limbal clearance, problems with back surface junctions, and hypoxia related to material (glass).

In 1983, Ezekiel [3] reported the use of gas permeable material in a scleral or 'haptic' lens solving the problem of hypoxia. This innovation was applied successfully in that decade in innovative lens designs at centers of excellence around the world [4–6]. Pullum and Buckley [7••] present the history and principles behind current scleral RGP lenses, with particular attention to the use of scleral RGP lenses in the management of ocular surface disorders. In summary, once hypoxia was conquered by high *Dk* materials, lens suction was the next challenge. Suction was circumvented, literally, by fenestration, which allows for air ventilation, or by haptic design with channels or contours that allow for fluid ventilation with no intrusion of air bubbles. Some lenses are described as sealed, with insignificant or no tear exchange. Air ventilation is often satisfactory for eyes with optical indications such as keratoconus or postkeratoplasty astigmatism, but air bubbles are typically not well tolerated in ocular surface disease.

In addition to scleral and corneal RGP lenses, there are lenses described as 'mini-scleral', 'semi-scleral', and 'cornea-scleral' RGP lenses in the literature. Indeed, there is a continuum between these and scleral lenses with diameters ranging between 14.5 mm and 24 mm. For

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the purpose of this paper, we will review papers on any RGP lenses intended to cover the limbus. The haptic designs of the smaller lenses vary, as well as the amount of corneal touch allowed in the fit; generally are all fluid-ventilated.

Scleral rigid gas-permeable lenses for ocular surface disease

In the past year there have been four publications documenting utility of fluid-ventilated scleral RGP lenses for ocular surface disease. Three of these are case series of single disease entities reporting outcome measures demonstrating the effectiveness of scleral RGP lenses.

Scleral rigid gas-permeable lenses for ocular chronic graft-versus-host disease

Takahide *et al.* [8**], in a collaborative report emanating from the Fred Hutchinson Cancer Research Center (Seattle, Washington), City of Hope National Medical Center (Los Angeles, California), and the Boston Foundation for Sight (Needham, Massachusetts, USA) report the use of a custom-designed, fluid-ventilated, gas-permeable scleral lens, the Boston Scleral Lens (Boston Foundation for Sight, Needham) for management of severe keratoconjunctivitis sicca secondary to chronic graft-versus-host disease (cGvHD). Their retrospective analysis found that there was improvement of ocular symptoms, reduced use of topical lubricants, improvement in the Ocular Surface Disease Index, and reduction of disability with daily scleral lens wear in nine consecutive cGvHD patients referred for scleral lens fitting between April 2004 and July 2006 for severe keratoconjunctivitis sicca that was unresponsive to standard treatments. They reported that there were no serious adverse events or infections attributable to the scleral lenses. The authors concluded that the use of the scleral lens appears to be safe and effective in patients with severe keratoconjunctivitis sicca, associated with cGvHD, refractory to conventional therapies.

In a separate report, Jacobs (this author) and Rosenthal [9**] from the Boston Foundation for Sight described 33 consecutive patients with severe dry eye from cGvHD who were fitted with the Boston Scleral Lens Prosthetic Device (updated name for the Boston Scleral Lens) between December 2002 and February 2005. Using a retrospective survey, they found that daily wear of Boston Scleral Lens Prosthetic Device resulted in improvement in pain, photophobia, and general quality of life in nearly all patients, with more than half reporting the highest improvement level for pain (52%) and photophobia (63%), and more than two thirds (73%) reporting the highest improvement level for quality of life. They found improvement in reading and driving in over 90% of those

who reported previous compromise, with over 60% reporting the highest improvement level for each of these activities. They report corneal neo-vascularization in three patients with additional predisposing factors, and no occurrences of infectious keratitis. The authors concluded that the Boston Scleral Lens Prosthetic Device mitigates symptoms and improves quality of life in patients with severe dry eyes from cGvHD.

Together these papers suggest that scleral RGP lenses represent an important therapeutic option for ocular surface disease in graft-versus-host disease, despite the fact that these patients might otherwise be considered poor contact lens candidates. Both series are limited by their retrospective nature, and in the larger series [9**], the use of a nonvalidated survey instrument. The duration of follow-up in these two series ranged from 1 week to over 2 years. The Boston Scleral Lens (Prosthetic Device) is unique among RGP scleral lenses in that its design features allows customization of haptic contour and control of vault independent of base curve through the use of spline functions. These features allow elimination of all corneal touch and an expanded pre-corneal tear film. The intent of these features was to accommodate ectasia, but the design resulted in the incidental creation of a 'liquid corneal bandage', which has proven therapeutic in eyes with ocular surface disease [10,11]. Toricity can also be incorporated into the haptic design improving lens tolerance and fit on eyes with toric sclerae.

Of note, there is a report of the safety and efficacy of extended wear soft lenses in the treatment of cGvHD [12*]. This well designed, prospective study found improvement in best corrected visual acuity and in symptoms (using the Ocular Surface Disease Index) and no adverse events or complications in eight patients. These patients were studied for only 1 month. Russo *et al.* note that 'further study is warranted with a larger sample size and various causes of dry eye disease for a longer study period to verify the safety of this treatment modality'. It is this author's experience that patients with cGvHD who benefit from a trial period of extended wear of a soft lens, derive even greater relief of symptoms from daily wear of a scleral lens, without incurring the additional theoretical risk of extended lens wear on a long term basis. Intolerance of a soft lens does not preclude tolerance of a scleral lens.

Scleral rigid gas-permeable lenses for atopic keratoconjunctivitis

Margolis *et al.* [13**] report that scleral RGP contact lenses are useful and safe to use in the management of the ocular surface and in the visual rehabilitation of eyes with medically controlled advanced atopic

keratoconjunctivitis sicca, in their series of 10 eyes in six patients followed for a median of 20.5 months. Their patients were fitted with Medlens Innovations lenses (Front Royal, Virginia, USA) of Equalens II material (Polymer Technology, Wilmington Massachusetts, USA). Three of six patients were intolerant of corneal RGP lenses. The authors report 'an improvement in conjunctival hyperemia, chemosis, and corneal epithelial defects in all eyes' and 'no complications or infections were observed from [scleral contact lens] wear'. They report statistically significant increase in the median visual acuity, as well as improvement of at least two lines in nine of 10 eyes. The authors conclude, 'Despite these few patients, differences in treatment regimens, lack of randomized control, and limited follow-up, we conclude that [scleral contact lenses] are effective and safe to use in treatment of the ocular surface and visual rehabilitation of patients with this complex and potentially devastating disease'.

Scleral rigid gas-permeable lenses for exposure keratopathy

Williams and Aquavella [14**] report the management of exposure keratopathy associated with severe craniofacial trauma with a scleral RGP lens (Boston Scleral Lens, Boston Foundation for Sight, Needham, Massachusetts, USA) and subsequent cataract extraction and intra-ocular lens (IOL) implantation with calculation of IOL power requirements through the scleral lens. The authors conclude, 'in patients with exposure keratopathy associated with significant craniofacial trauma, traditional treatment measures such as aggressive lubrication, tarsorrhaphy, platinum lid weight implantation, punctual plugs, correction of lid retraction, amniotic membrane application and multiple bandage contact lenses may fail. In these challenging patients, scleral lens placement may be necessary to permit sufficient protection and healing of the cornea'. These authors report (and it is this author's experience) that Boston Scleral Lens wear can be resumed in the first postoperative week after cataract extraction in the presence of a secure wound.

Scleral rigid gas-permeable lenses in the treatment of pediatric patients

Gungor *et al.* [15**] report one center's experience fitting the Boston Scleral Lens in pediatric patients. In this retrospective medical record and database analysis, experience with 31 patients, ages 7 months to 12.92 years, who were fitted with scleral lenses from 1996 to 2006 was described. Twenty-seven of 31 patients were fitted for ocular surface disease rather than refractive disorders, with congenital corneal anesthesia and Stevens–Johnson syndrome each accounting for over one third of patients. The mean duration of documented

scleral lens use was 24 months. Clinicians treating children with ocular surface disease should be aware of scleral RGP lenses as a therapeutic option for their young patients.

Reports of innovative scleral rigid gas-permeable lens designs

Visser *et al.* [16**] report on 178 patients fitted in their scleral lens practice in The Netherlands who had been wearing one or two RGP scleral lenses for at least 3 months during the entry period from in September 2002 to January 2003. Their lenses were of design and manufacture by Procornea (Eerbeek, The Netherlands), incorporating four possible designs. Their fitting goal was for fluid-ventilation with corneal clearance 0.25 mm and 0.05–0.10 mm limbal clearance. They report increased visual acuity and safe physiological response of the anterior eye with continued wear of the lens in all patients. Study design excluded patients with fit or early wearing failure. Fifty percent of eyes were fit for keratoconus and 20% for prior keratoplasty, with ocular surface disease accounting for a minority of patients. Visser *et al.* conclude, 'the satisfactory clinical performance of modern scleral lenses meant that their continued application can be recommended in all cases'.

In an accompanying paper [17**], the same group reports on the result of oral surveys of retrospective satisfaction with prior correction, and current scleral lens correction in this same group of 178 patients. Median duration of current scleral lens type was 10.7 months. The authors report significant increase in score in comfort, visual quality, and overall satisfaction in over 75% of patients with the current scleral lens compared to all types of prior correction. This study is limited by the retrospective nature of the satisfaction survey and the fact that patients not fitted, fit failures, and wearing failures were not included. The authors broke down the satisfaction dimensions by their four lens designs and found higher satisfaction with back-surface toric as compared to back-surface spherical designs. They conclude, 'Optimized physical fitting of back-surface toric scleral lenses with toric bulbi resulted in greater patient satisfaction'. Patient satisfaction with the Procornea lens and Boston Scleral Lens may be in part due to the ability to accommodate toric sclerae.

Ye *et al.* [18*] report that Jupiter mini-scleral RGP lenses (Innovations in Sight, Front Royal, Virginia, USA) were used for visual rehabilitation in three patients: one with graft-versus-host disease, one with Terrien's marginal degeneration who failed corneal lens wear, and one with keratoconus who failed corneal lens wear. These lenses were all fitted flatter than the manufacturer's recommendation, thus some corneal

touch is a likely feature of the fit in this report; the authors reported that steeper fits resulted in intrusion of air bubbles. They did not report on duration of follow-up in their patients.

Conclusion

Scleral RGP lenses are an underappreciated option in the treatment of patients with ectasia, irregular astigmatism, and ocular surface disease. The special design features of modern scleral RGP lenses allow for successful fitting of ectatic and astigmatic eyes and those with toric sclera. Modern fluid-ventilated scleral RGP lenses create an expanded precorneal tear film over the ocular surface; some designs do not contact the cornea at all. These modern designs may increase therapeutic potential, lens tolerance, and patient satisfaction. There is a growing body of evidence that scleral RGP lenses represent an important therapeutic option in ocular surface disease in cases that do not respond to conventional therapy.

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References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 365).

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