Treatment of ocular surface disorders and dry eyes with high gas-permiable scleral lenses

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Abstract

Extreme corneal surface disorders and dry eye conditions cannot be adequately treated with corneal contact lenses. For these cases a scleral lens with a diameter of between 21 mm and 25 mm could be prescribed. In this study high oxygen-permeable scleral contact lenses were fitted onto 50 eyes of which 32 had a deviant corneal topography and 18 had dry-eye syndrome. A significant improvement of visual acuity and good lens tolerance were found. The large lens successfully created a moist atmosphere in front of the cornea with dry-eye circumstances. No signs of oxygen shortage were recorded. In three dry eyes (16.7%) immediate failure in fitting was found, due to lens binding. The new scleral lens provides a physiological condition of the cornea, which allows a revival in the application of such lenses.

Introduction

The practical clinical development of contact lenses began with the work of Fick, now more than a century ago (1). He fitted lenses with a scleral or haptic design which were made out of glass. During the period 1920 - 1930 the preformed trial fitting set, as we know it today, began to emerge. The use of plastics, to overcome some of the technical difficulties associated with the manufacture of glass lenses, was introduced by Feinbloom (2). Application of these lenses was, however, limited by the short wearing time due to severe corneal hypoxia, resulting in corneal edema.

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The development of corneal lenses (from 1948 onwards) and hydrogel lenses (from 1970 onwards) restricted the use of scleral lenses to special applications performed at only a few centers in the world. Several severe pathologic conditions warrant the use of a scleral lens. This is the case when corneal lenses are precluded by peculiarities of corneal topography, keratitis sicca or defective eyelid conditions. In the last decade the advent of rigid oxygen-permeable materials has greatly reduced the anoxic complications associated with rigid contact lens wear, opening new perspectives for the use of scleral lenses.

Ezekiel (3) and Ruben (4) reported the first successful use of oxygen-permeable scleral lenses made of Boston II rigid silicon/acrylate copolymer (Dk = 14.8 x 10^{-11} cm^2 ml O_2/sec ml mmHg at 35° C). Further advances in the development of high oxygen-permeable materials have occurred

during the past five years. Successful fitting of high gas-permeable scleral lenses, made of rigid fluoro-silicone/acrylate copolymer (Itafluorofocon B) with a Dk of 110 x 10^{11} cm^2 ml O_2/sec ml mmHg at 35° C was recently reported by Schein (5). We have extended the findings mentioned above and now report the clinical results of 50 consecutive fittings with a high gas-permeable scleral lens in patients with deviant corneal topography and dry-eye syndrome. The scleral lenses used resulted in a marked improvement in the visual acuity in these patients and did not adversely affect their corneal physiology.

Material and methods

A total of 50 eyes (37 patients) was fitted with the new scleral lens. Two patients (three eyes) showed fitting failures at the beginning of the study due to their serious dry-eye condition of Sjögren's Syndrome. The data of these patients are not shown. Of the remaining 35 patients, 15 were male and 20 were female patients. The mean age was 42.9 years (s.d. 18.6 years; range 16 - 78 years). The mean follow-up per eye was 23.6 months (s.d. 8.5 months; range 11 - 42 months).

Thirty-two eyes (25 patients) proved to be intolerant or were a fitting failure with conventional contact lenses because of deviant corneal topography. Corneal surgery was contra-indicated in these cases. The diagnoses of these patients included were: keratoplasty, cornea plana, corneal scar, pellucid marginal degeneration, radial keratotomy, keratopathy by ectodermal dysplasia and keratoconus (Table I).

Fifteen eyes (11 patients) had keratitis sicca, which did not respond to conventional therapy with artificial tear substitutes or soft bandage lenses. In the case Of neuroparalytic keratitis and Graves ophthalmopathy the dry-eye condition was caused by exposure. In all other cases the Schirmer test values ranged from 0 mm to 3 mm, indicating severely reduced tear production. The diagnoses of the patients included in our study for keratitis sicca were: neuroparalytic keratitis, Sjögren's Syndrome, neurogenic keratitis, keratitis after irradiation, Graves ophthalmopathy and some cases with an unknown etiology (Table II).

The rigid high oxygen-permeable scleral lenses were made of fluoro-silicone/acrylate copolymer (Dk 110 x 10^{-11} cm^2 ml O_2/sec ml mmHg at 35° C). The lens has a lathe cut multi-curve spherical geometry of the posterior lens curve. Usually the lens has three spherical curves.

The first (optical) curve is determined after trial lens fitting. The second, intermediate, curve is a blending curve. The third curve of the periphery of the lens is calculated equal to a sagittal depth

Table I

Patient categories fitted with high gas-permeable scleral lenses (N = 47 eyes)

Deviant corneal topography	(N = 32)	Number of eyes	
- Keratoplasty	Keratoconus	(kc)	9
	cornea dystrophy	(cd)	1
	keratoglobus	(kg)	2
	iatrogenic	(ia)	2
	unknown aetiology	(un)	2
- Cornea plana		(Cp)	4
- Keratoglobus		(kg)	4
- Corneal scar after trauma		(Cs at)	2
- Corneal scar after irradiation		(Cs ir)	1
- Pellucid marginal degeneration		(Pm)	2
- Radial keratotomy		(Rk)	1
- Keratophaty by ectodermal dysplasia		(K ed)	1
- Keratoconus		(Kc)	1

Table II

Keratitis sicca (N = 15)			
- Keratitis sicca (Ks)	neuroparalytica	(np)	4
	Sjögren's Syndrome	(Ss)	3
	neurogenic	(n)	1
	after irradiation	(irr)	2
	Graves ophthalmopathy	(Go)	3
	unknown etiology	(un)	2

of an aspheric lens eccentricity (E) value of 1.2. On the convex side, two curves are made with an optical zone which is equal to the optical zone on the inside of the lens. The central thickness is 0.4 mm - 1.5 mm, depending on lens power. The edge of the lens and the junction between the lenticular part and the carrier zone are minimally 0.8 mm thick. No fenestrations, channels, slots or truncations were necessary.

The lenses were fitted with the use of a preformed fitting set (Table III). Different lenses were tried until an ideal scleral fit with minimal corneal and limbal clearance was obtained. Tear exchange was checked by the instillation of fluorescein in the fornix and the subsequent distribution under the lens was evaluated after blinking.

For statistical analysis a paired t-test was used. The data of two eyes of the same patient were averaged to rule out the factor of dependency.

The wearing time was restricted to 4 hours at the beginning of lens wear. Each day 2 hours of additional wearing time were allowed. Dry-eye patients were advised to take the lens out after a maximum of 4 hours. Afterwards the lens was refilled with non-preserved isotonic sterile saline solution before reinsertion to provide a lacrimal interface. In some cases additional Vidisic gel® was used to prolong the liquid lacrimal interface and/or to avoid air bubbles under the lens during insertion. The lenses were cleaned with Boston lens cleaner and stored in Boston conditioner solution.

Wearing time was scored as follows: less than 4 hours, 4 - 8 hours, more than 8 hours. Other clinical parameters which were recorded included: visual acuity with spectacles and with the scleral lens; slit-lamp findigs; central keratometry

Table III

Lens specifications of preformed fitting set consisting of 18 lenses

No	Back optic zone radius (mm)	Back scleral zone radius (mm)	Back scleral size diameter (mm)	Lens power (Diopters)
1/2	650	12.5/13.5	22	− 11
3/4	750	13.0	22/23	− 2
5/6	750	13.0	22/23	+ 13
7/8	850	13.0	22.5/23.5	+ 4
9/10	850	13.0	22.5/23.5	+ 19
11/12	780	12/12.5	22	plano
13/14	idem	13/13.5	idem	idem
15/16	820	12/12.5	22	+ 2
17/18	idem	13/13.5	idem	idem

readings; pachymetry before and after lens wear in a randomly selected group of patients.

The earlier use of glass and PMMA scleral contact lenses was complicated by oxygen shortage under the contact lens, resulting in corneal edema, also known as Sattler's veil. The corneal swelling response was measured in 20 randomly selected cases to determine whether the new scleral lens transmits sufficient oxygen to supply the minimum corneal need.

For pachymetry measurements a modification according to Mishima (6) was used on the Haag-Streit Slit-lamp. The tear layer was coloured with fluorescein to make the measurements more accurate. Measurements were performed before lens wear and after a wearing time of three months. Corneal thickness was recorded after at least 4 hours of lens wear.

Results

Two patients (three eyes) showed immediate fitting failure at the beginning of the study due to their dry-eye condition associated with Sjögren's Syndrome. The lenses adhered to the eye of these patients and were very difficult to remove. A reasonable wearing time was never reached. The painful corneal lesions, caused by removal of the lens, were the reason for their refraining from any further lens wear. These patients were not motivated to try a different lens.

Visual rehabilitation is one of the main goals in fitting scleral lenses. A statistically significant improvement (p 0.001) of the visual acuity was observed in all ayes with the new lenses. The mean spectacle-corrected Snellen visual acuity in decimals was 0.28, which correlates with 20/70, and the mean vision with the scleral lens was 0.70, which correlates with 20/30. The best results were found in the group with deviant corneal topography. Most of the keratitis sicca patients also experienced an important improvement in visual acuity.

The treatment of a severe dry-eye condition was successful in 13 eyes (10 patients), as expressed by good comfort and a wearing time of at least eight hours. One patient with severe dry eyes after irradiation had a limited wearing time of less than four hours. Deposit formation on the surface of the lens and behind the lens after a limited wearing time of two to three hours resulted in an uncomfortable hazy vision. To restore good visual acuity with the lenses, however, was much better than with spectacles, due to the irregularity of the corneal surface. For this reason the patient was motivated to wear the lenses for a limited period of time.

The central part of the corneal topography was measured with a keratometer. In some cases the irregularity of the cornea prohibited accurate readings to be made. The mean corneal astigmatism was 4.8 (s.d. 4.3; range 0.0 - 17.4, N = 40). No warpage of the cornea was noted during the study. No statistically significant difference was found between the first horizontal keratometer readings (mean = 7.93 mm, s.d. 1.30 mm) and the second horizontal keratometer readings (mean = 7.94 mm, s.d. 1.29). Likewise the first vertical keratometer readings (mean = 7.86 mm, s.d. 1.38 mm) and the second vertical keratometer-readings (mean = 7.86 mm, s.d. 1.40 mm) did not show a significant difference.

Corneal thickness before lens wear (mean = 0.48 mm, s.d. 0.10) and after lens wear (mean = 0.47 mm, s.d. 0.12) was not significantly altered.

With the previously used glass and PMMA scleral lenses the wearing time was limited to a maximum of four to five hours. With the high gas-permeable scleral lenses the wearing time reached a daily wear schedule for most of the cases. The wearing time was less than four hours in four patients (11.8%), four to eight hours in two patients (5.7%) and more than eight hours in 29 patients (82.9%).

Few side effects were recorded with the slit-lamp. Mild fluorescein staining of the cornea was found in 6 cases (12.8%). Epithelial edema was noted in four eyes (8.6). No microcysts, striae nor Descemet's folds were found. No patient was excluded from the study based on these side effects.

Discussion

The advent of high oxygen-transmissible corneal soft and rigid contact lenses has disminished the use of scleral lenses as a therapeutic device. A number of severe pathologic conditions of the cornea, however, cannot be adequately treated with corneal lenses. Severe ocular surface disorders, dry-eye conditions and eyelid defects warrant the use of a scleral lens. The new high oxygen-permeable fluoro-silicon acrylate copolymer lens materials may indicate a new future for scleral lens fitting (3-5).

The good visual acuity and good scleral lens tolerance found in this study were recorded in cases of abnormal anterior segment topography and dry ocular surface disease. For both groups of patients conventional therapy had failed. For the group of patients with a deviant corneal topography the improvement of visual acuity, which enables them to resocialize, is considered to be the main advantage of this new lens. These findings confirm the clinical observations recently reported by Schein (5), showing successful treatment of corneal topography disorders with gas-permeable scleral lenses. We extended these studies showing that these lenses can also be used to treat patients with dry-eye syndrome.

Insufficient wetting of the cornea may result in epithelial defects and scarring with subsequent loss of vision. The treatment possibilities of severe dry eyes due to exposure or lack of tear production have been limited and often unsuccessful. The use of the scleral lens was satisfactory in the treatment of 15 out of 18 dry eyes. The main advantage of the scleral lens in the dry-eye patient is that a moist atmosphere is created in front of the cornea, while evaporation is limited by covering the cornea with the large lens. By fitting a dry eye in such a way as to achieve an excess overall corneal clearance, a precorneal space is created which may act as a reservoir for liquid. Disturbance of corneal physiology by the wearing of contact lenses may result in changes in corneal shape and swelling of the cornea (7,8). In rigid corneal contact lens wear the corneal contour may change due to mechanical influences (7). Our fitting technique uses apical clearance in combination with minimal pressure at the sclera, to avoid apical corneal contact as much as possible. This may be seen as the main reason for the stable central corneal topography, wich was determined by central horizontal and vertical keratometry in our study.

The shortage of oxygen under a glass or PMMA scleral lens has limited the wearing time and therefore restricted their application. Oxygen levels that prevent corneal edema and anaerobic metabolism by using (low) oxygen-transmissible lens material (Dk 14.8 - Dk 27) have been reported earlier (3, 4). To evaluate whether a contact lens provides the minium corneal oxygen requirement, three methods can be used: 1) Equivalent Oxygen Percentage (EOP) measurement 2), Transmissibility (Dk/L) measurement, 3) Corneal swelling response measurement (8).

The Equivalent Oxygen Percentaje level under static lens conditions for fluoro-silicone materials is calculated to be approximately 10 for a lens 0.5 mm thick (8), wich is considered to satisfy the basic corneal requirement (9). The additional oxygen that is provided by tear exchange under the lens may be added directly to the EOP curve. As yet the precise contribution of tear exchange during scleral lens wear is unknown.

As the permeability of lens materials approaches that of the tear film (Dk 78) itself, even the parameter Dk/L loses its accuracy as a predictor of the cornea response as a result of the boundary layer effect (10). Furthermore, a considerable spatial variation in lens thickness will be present between plus- and minus-power scleral lenses. These two factors make Dk/L calculations inappropriate for high Dk scleral lenses.

The corneal swelling response varies as a function of the level of oxygen transmitted by the lens (8). No statistically significant corneal swelling response was recorded in this study, as measured by corneal pachymetry in a limited group of patients. Furthermore, only a limited number of clinical findings that are related to oxygen shortage of the cornea, (epithelial edema, microcysts, striae, Descemet's folds) were observed. A combination of the high oxygen transmissibility of the lens

material and the tear exchange wich is obtained by a fitting technique with apical and limbal clearance may be responsible for maintaining a normal corneal physiology.

The scleral lenses were comfortable for a wearing time of at least eight hours in 80% of the cases described. This may be seen as a considerable step forwards as compared with the previously used PMMA lenses wich had a maximum wearing time of four to five hours in a healthy eye.

Compared with conventional PMMA scleral lenses, the most important advantage of the gas-permeable scleral lenses is the physiological implication on the cornea. Because of this, there is a new perspective for the use of scleral lenses when treatment with corneal lenses fails.

Case histories

The new approach to lens fitting of high oxygen transmissible and dry eyes is illustrated by the following cases.

Case 1

A female patient, 42 years old, had a car accident some 15 years ago. After a severe trauma capitis a neurogenic keratitis sicca was diagnosed. The schirmer test revealed 0mm - 1mm for both eyes. There was a continues need for artificial tears. Successful therapeutic therapeutic therapy like closure of the punctae and therapeutic soft lens wear was tried. However visual acuity of the left eye was lost by severe scarring. Scarring of the right eye resulted in a irregular corneal surface. A piggy-back lens system for the right eye, consisting of a soft bandage lens with a rigid lens on top, improved the visual acuity of the right eye. However, the dry eye condition prohibited successful contact lens wear.

In 1986 the visual acuity of the right eye with spectacles was less 20/200. The patient was socially handicapped, unable to read and forced to use artificial tears several times an hour to prevent further scar formation. Keratometric readings were: 7.96 x 7.87. The patient was fitted with a new scleral lens with the following parameters: 8.20/+1.25/23.5. The visual acuity with the scleral lens improved to 20/20. This changed her social life dramatically, including the ability to read again. The wearing time was unrestricted. The lens was inserted with saline line solution. After four hours of wearing the lens was removed and reinserted with saline line solution.

A follow up of four years was realised without any adverse reactions.

Case 2

A male patient, 41 years old, is member of a family with brittle bones, blue sclerae and keratoglobus. The left eye was lost as a boy of 9 years old after failure of two penetrating keratoplasties. the patient was wearing spectacles with the following specifications: S -6 = C -16 x 150°. Corrected visual acuity was 4/60. The corneal topography with irregular keratometric readings less than 5.5 prohibited the wearing of corneal contact lenses. Corneal thickness was measured to be 0.18mm. The patient was unable to work under these conditions. With the help of a high oxygen transmissable scleral lens with the following specifications: 6.20/-10.0/22.5, visual acuity improved to 20/30. The wearing time was unrestricted. No corneal complications were noted.

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