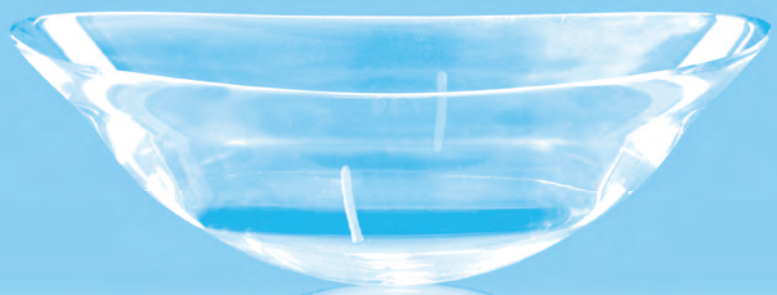
Objective and subjective performance of scleral lenses and new advances in scleral lens technologies

Esther-Simone Visser



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Objective and subjective performance of scleral lenses and new advances in scleral lens technologies

Objectieve en subjectieve behandelresultaten van scleralenzen
en innovaties in scleralenstechnieken
(met een samenvatting in het Nederlands)

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Chapter 1

General introduction and outline

General introduction

Scleral lenses are widely recognized for their ability to markedly improve quality of life and giving back patients their ability to perform daily activities, mainly as a result of restoring visual function and/or reduction of ocular discomfort and pain.[1,2] Scleral lenses are an important front-line tool for managing many corneal disorders refractory to other treatment measures and that otherwise would require keratoplasty.[3] These disorders include conditions in which the cornea requires suitable optical correction in irregular surface,[3-7] as well as to relieve symptoms, provide mechanical correction and/or facilitate corneal healing in ocular surface disease.[3,8-12]

Scleral lenses are large-diameter, rigid-gas permeable contact lenses that rest on the external sclera (conjunctival layer) and vault the cornea and limbus (Figure 1). The fluid reservoir (also referred to as the clearance) between the scleral lens and the cornea can neutralize an irregular surface and can help hydrate and protect the corneal surface (Figure 2). Moreover, the rigid nature of the lens material provides both mechanical protection and optical correction of the corneal surface.

Interest in scleral lenses has increased considerably in recent years due to technological innovations with respect to the materials used. In addition, the design and manufacture of scleral contact lenses has led to improved lens-fitting characteristics and performance. The field has also seen an increase in the accessibility of diagnostic fitting lens sets and lens-fitting expertise. This growing interest is reflected in the important role that scleral lenses play in rigid gas-permeable (RGP) lens fittings in many countries, and in the large number of reports regarding scleral lenses at international conferences and in the published literature.[1]

The fundaments for the research projects in this thesis started with the development of two key innovations (back-surface toric and tangential design) in scleral lenses by our team. These innovations are important steps towards maximizing patient comfort and optimizing scleral lens performance. The clinical and patient-oriented benefits of these internationally renowned breakthroughs are discussed in this thesis.

This thesis starts with a general introduction of the fundamental properties, complications, and indications of scleral lenses. Subsequently the role of scleral lenses in the context of other contact lens types is examined and made accessible for practitioners, by supplying a lens selection algorithm. Furthermore the focus of the research is on the indications and performance of modern scleral lenses, including the recent advances in scleral lens technologies (i.e., back-surface toric and tangential scleral lenses). Lastly, the use of scleral

lenses following a relatively new treatment option for keratoconus (corneal crosslinking, or CXL) is evaluated, and the effect of scleral lens use on corneal physiology is examined.

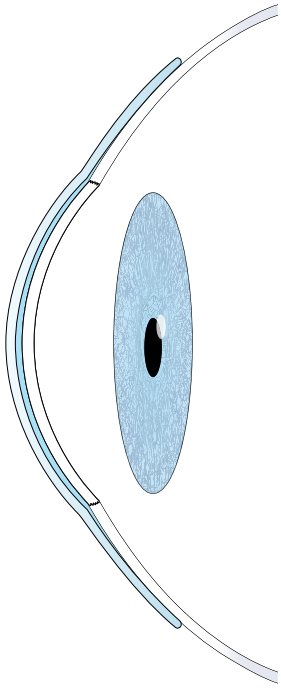

Figure 1. Schematic representation of a scleral lens on-eye.

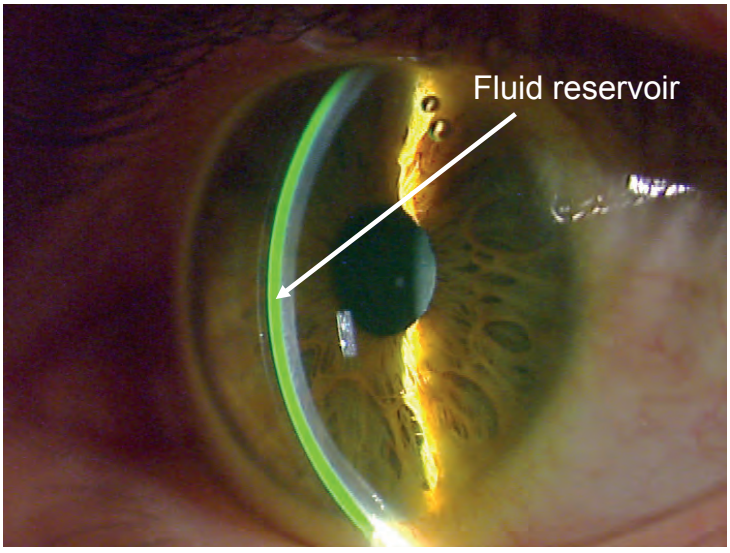

Figure 2. Fluid reservoir between the scleral lens and the cornea stained with fluorescein.

A brief history of scleral lenses

From the sixteenth century and on…

The first tangible steps in the development of contact lenses came from several early pioneers, including Da Vinci in the 16th century, Descartes in the 17th century, and Young at the turn of 18th and 19th centuries.[13,14] These visionaries were the first inventors to describe the concept of neutralizing the corneal surface using water to change the refractive power of the eye, and this thoughts steps preceded the independent and simultaneous development of the first contact lenses (made of glass) in the late 19th century by Fick, Müller, Kalt, and Himmler.[15-19]

The 1930s saw the development of impression molding techniques, which led to increased interest in scleral contact lenses for the use of several therapeutic indications.[20-22] The availability of the lightweight plastic material polymethyl methacrylate (PMMA) around the time of the Second World War improved the manufacturing of the lenses; however, with this material, patients often developed corneal edema due to severe hypoxia, which restricted wearing time.[23] Despite the optimization of both tear flow and corneal oxygenation with the introduction of ventilation designs such as channels or fenestrations,[24,25] PMMA-based scleral lenses still produced an unacceptable level of corneal hypoxia.[26] Following the introduction of corneal contact lenses in 1948 and hydrogel lenses in the 1970s, interest in scleral contact lenses waned considerably, as these new types of lenses overcame many hypoxia-related problems and were easier to fit. However, scleral lenses were still prescribed for managing certain corneal conditions for which other lenses or treatments were not feasible.[22,24,27-31]

To gas-permeable materials and beyond…

The successful use of gas-permeable haptic lenses by Ezekiel[32] in 1983 was an important milestone, as these lenses significantly reduced the risk of hypoxic complications, were easier to fit, and were more comfortable to wear.

The first successful results using highly gas-permeable materials were seen with preformed scleral lens fitting methods, which yielded good lens tolerance and provided safe and effective treatment.[4,8,33-37]

The 1990s was a hallmark decade in the modern development of scleral contact lens design. First, the application of a front-surface cylinder was introduced to improve vision.[38,39] Next, a breakthrough—the back-surface toric scleral lens—was introduced by our team and is discussed in Chapters 3 through 5. Importantly, studies regarding corneal shape confirmed

our clinical experience with back-surface toric lenses by demonstrating that the shape of the anterior sclera is often asymmetrical (i.e., one or more segments of the sclera are either steeper or flatter than other scleral segments).[40,41] Moreover, these studies revealed that the shapes of the cornea-scleral junction and the anterior sclera are often tangential rather than curved,[1,40,42] prompting the development of bitangential shaped scleral lenses, which are discussed in Chapter 6. The current use of nonrotationally symmetrical scleral lenses (i.e., back-surface toric lenses or quadrant-specific scleral lenses) has been reported.[12,43-46] Furthermore, the highly oxygen-permeable material Menicon Z (Menicon Co. Ltd., Nagoya, Japan) was introduced; this material can be particularly beneficial to patients whose corneas have high oxygen demand.

Other areas of recent research in scleral lens design include the incorporation of bifocal, prism and higher-order aberration correction,[47,48] as well as the use of optical coherence tomography (OCT) for designing scleral lenses.[49]

Additional areas of current scleral lens research focus on the indications for prescribing scleral lenses, the effect of scleral lenses on the cornea, and complications associated with scleral lens use.

Fundamental properties of scleral lenses

Nomenclature

Scleral lenses differ from corneal and corneo-scleral lenses because they rest entirely on the anterior sclera and vault the cornea and limbus. Scleral lenses can be best classified based on the bearing area on the ocular surface (e.g., cornea and/or sclera), because classifications based solely on the lens' diameter is not sufficient in cases of extremely large or small eyes.

The Scleral Lens Education Society has developed an internationally recognized classification system that defines scleral lens types based on the bearing zone area of the lens on the ocular surface (Table 1).

Table 1. Nomenclature used for corneal, corneo-scleral, and scleral lenses.

Lens Type	Description	Definition of Bearing Area
Corneal		Lens rests entirely on the cornea
Corneo-scleral		Lens rests partly on the cornea, partly on the sclera
Scleral	Mini-Scleral *Lens is up to 6mm larger than HVID*	Lens rests entirely on the sclera
	Large Scleral *Lens is more than 6mm larger than HVID*	

HVID = horizontal visual iris diameter.
(adapted from the Scleral Lens Education Society (www.sclerallens.org) 2015, with permission)

Scleral lenses are categorized as either large-scleral lenses or mini-scleral lenses (Figure 3). In addition to the obvious difference in size, large-scleral and mini-scleral lenses differ in the amount of clearance that can be established between the lens and the cornea; specifically, the fluid reservoir capacity of mini-scleral lenses is relatively small, whereas this capacity is essentially unlimited with a large-scleral lens. Therefore, large-scleral lenses are typically indicated in cases that require increased corneal and/or limbal vaulting, for example when the cornea protrudes more extremely, which can occur in advanced keratoconus, keratoglobus, and keratoplasty. Large-scleral lenses are also recommended in cases that require increased bearing and/or increased protection of the ocular surface, and in cases in which tear film production is diminished. In contrast, mini-scleral lenses are indicated in cases that require decreased scleral bearing due to local topographical elevations, for example with scleral nodules or following surgery (e.g., blebs or implants following glaucoma surgery), moreover they have less interference with peripheral scleral toricity. Mini-scleral lenses are also indicated in cases with a small aperture and in patients who are psychologically resistant to the larger scleral lenses; these patients generally find smaller lenses easier to insert and to become accustomed to.

In this thesis, unless indicated otherwise, the term “scleral lens” is used to refer to large-scleral lenses, as well-fitting mini-scleral lenses only recently became available in our practice. Our initial experiences with using mini-scleral lenses for the above-mentioned indications have yielded promising results, although their performance and full value are currently being investigated.

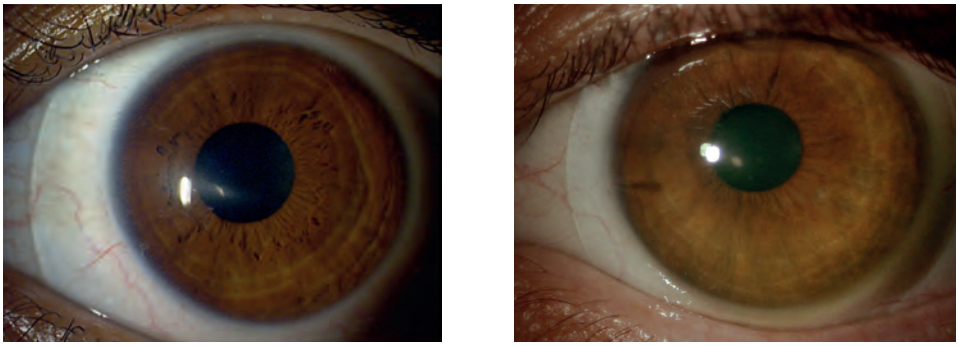

Figure 3. Large-scleral lens and mini-scleral lens on-eye.
Left: a large-scleral lens. Right: a mini-scleral lens.

Scleral lens design

Most scleral lens designs are based on a three-lens zone geometry that includes the optical zone (the central zone), the transition zone (mid-peripheral zone), and the scleral zone (landing zone) (Figure 4). Both a smooth transition between these zones and a well-defined lens edge are necessary in order to ensure gentle application to the ocular surface and interaction with the eyelids.

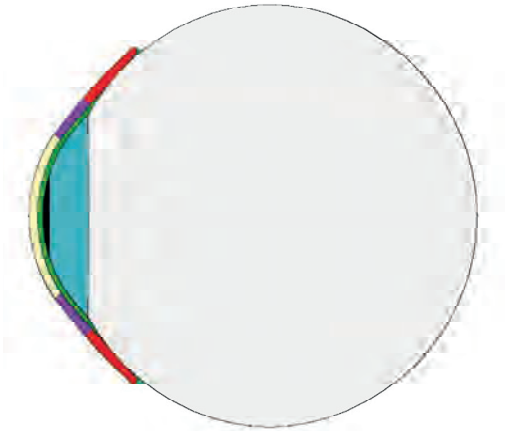

Figure 4. The three zones of a scleral lens.
The optical zone, transition zone, and scleral zone are shown in yellow, purple, and red, respectively.
(courtesy of B.J.J.J. van der Linden, with permission)

Each individual scleral lens can be defined using the following parameters: sagittal depth (i.e., height), central radius, scleral zone, and lens diameter; moreover, spherocylindrical lens power can be incorporated in the lens.

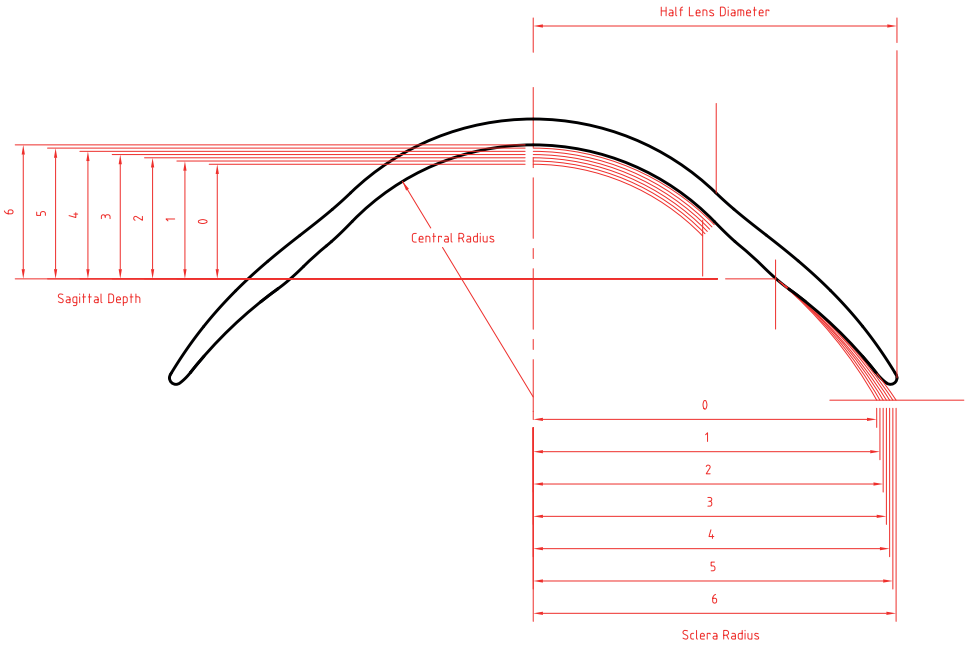

Figure 5. Schematic representation of a curved scleral lens.
(courtesy of B. Wanders, with permission)

With the classic curved scleral lens design (Figure 5), the scleral zone is defined by the scleral radius; a larger scleral radius results in a flatter-fitting scleral part. With the tangential scleral lens design (Figure 6), the scleral zone is linear (rather than curved), thus providing a more gentle bearing on a tangentially shaped sclera. This zone is thus described by tangent angles; a large tangent angle provides a steeper scleral fit, whereas a shallow angle provides a flatter scleral fit. With a back-toric (or even quadrant-specific) scleral lens, the scleral zone is toric and two or more separate scleral radii or tangent angles can be used.

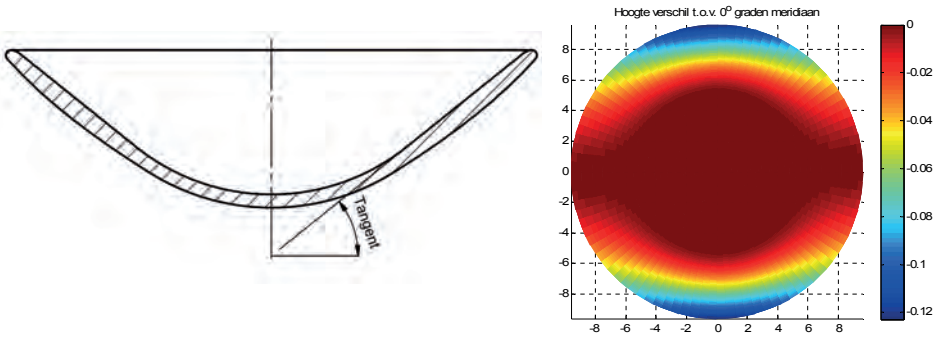

Figure 6. Schematic representation of a tangential scleral lens.
Left: tangent angle. Right: toric scleral zone with two separate tangent angles.
(courtesy of B.J.J.J. van der Linden, with permission)

Production and materials

Most modern scleral lenses are manufactured using precise submicron lathing of specially designed large-diameter blanks.

The materials currently available for making scleral lenses are either high-oxygen-permeable or ultra-high-oxygen-permeable materials. The materials that were used primarily in this thesis are summarized in Table 2. Materials with a higher Dk (oxygen permeability, D = oxygen diffusion coefficient, k = oxygen solubility of a contact lens material) value provide better oxygen supply to the corneal surface and are therefore the materials of first choice. However, materials with a lower Dk value have superior performance in terms of scratch-resistance. Moreover, the Equalens II material is less prone to collecting deposits on the lens surface.

Table 2. Scleral lens materials.

Trade Name	Boston Equalens II [a]	Boston XO [a]	Boston XO2 [a]	Menicon Z [b]
Generic name	Oprifocon A	Hexafocon A	Hexafocon B	Tisilfocon A
Dk	85[c]	100[c]	161[d]	189[d]
Wetting angle	30°	49°	38°	24°[e]
Plasma-treated	No	No	Optional	Yes
Prone to deposits	-	+	+	+/-
Scratch-resistance	+	+	-	-

Dk = oxygen permeability, D = oxygen diffusion coefficient, k = oxygen solubility of a contact lens material.
[a] Manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA, USA.
[b] Manufactured by Menicon Co. Ltd., Nagoya, Japan.
[c] Measured using the Polarographic ISO/Fatt method.
[d] Measured using the non-edge-corrected ISO/Fatt method.
[e] After plasma treatment.

Scleral lens fitting

Scleral lenses are generally fitted using trial lenses in a five-step fitting approach in which the total lens diameter, corneal and limbal clearance, scleral zone, lens edge, and asymmetrical lens design is considered.[50] Schornack and Patel[51] investigated the use of anterior corneal contour parameters in the fitting of scleral lenses; however, they concluded that the current diagnostic approach using trial lenses seems to be the most efficient method for fitting scleral lenses. Highly accurate OCT measurements might be used to fit scleral lenses in the future.[49,52] Another fitting method, impression molding, is used by only a few eye-care practitioners in extreme cases, specifically when the sclera is excessively toric or irregular.[53,54] However, the impression molding technique was refined recently by digitizing the mold of the eye, thereby creating a customized scleral device.[55]

The scleral lenses described in this thesis were fitted using the preformed standardized fitting methods developed in our practice. During the fitting procedure, the following five parameters are determined: sagittal height (in mm); the central radius (base curve radius or BCR; in mm); the tangent angles (in degrees) or scleral radii (in mm) of the flattest and steepest meridian of the scleral part; total lens diameter (in mm); and spherocylindric lens power.

Fitting is based on resting the lens on the external sclera and vaulting over the cornea and limbus. An optimal lens fit includes optimum corneal/limbal bridging and scleral fit; this is determined by use of a slit lamp after fluorescein has been applied to the fluid reservoir and the lens has settled for at least 20 minutes. Proper fitting requires a well-balanced bearing of the scleral zone in order to keep the peri-limbal region free of pressure; in addition, the lens should move gently upon push-up. The scleral zone can be adjusted by changing the scleral radius or tangent angle, the amount of back-surface toricity, and/or total lens diameter. The scleral zone can be assessed circumferentially using a slit lamp with the patient moving his/her eyes in all directions. However, the fit should be evaluated when the lens is in the primary position (or as close to the primary position as possible), as the scleral lens edge may have a false tight or loose-appearing fit due to lens decentration induced by eye movement. If the lens fit is too tight, blanching of the conjunctival vessels can occur; in contrast, a loose scleral fit can lead to air bubbles beneath the lens.[38,45,46,50] Examples of well fit and poorly fit scleral lenses are shown in Figures 7-10.

Figure 7. Well-balanced bearing of the scleral zone.

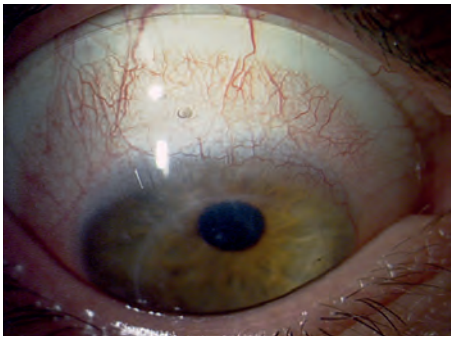

Figure 8. Blanching of the conjunctival vessels due to a tight-fitting scleral zone.

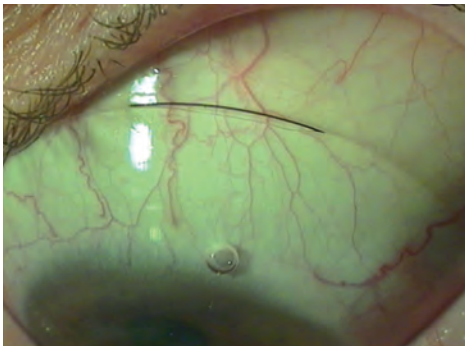

Figure 9. A loose-fitting scleral lens edge with a trapped air bubble.

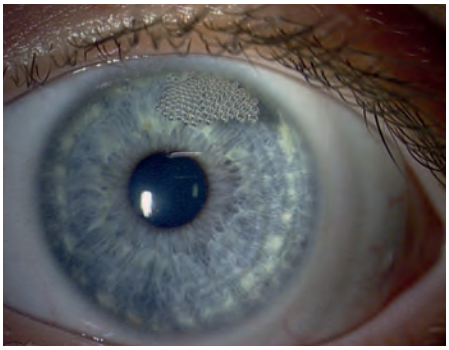

Figure 10. Trapped air bubbles behind a scleral lens.

Clearance (i.e., the “vault”) is the space between the lens and the cornea (Figure 2). The desired clearance based on clinical experience is approximately 0.2 mm centrally and 0.1 mm peripherally and can be adjusted using the sagittal height and central radius. In practice, clearance can be estimated using either lens thickness (the center thickness of trial lenses is standardized) or corneal thickness (if pachymetry measurements are available) as a benchmark. This can be measured using a narrow slit light that moves from limbus to limbus at a 45-degree angle. OCT can be used to determine clearance with high precision.[56] Insufficient clearance (i.e., contact) should be avoided, as this can result in mechanical pressure on the cornea, which can disrupt the corneal physiology, decrease comfort, and reduce tolerance. In addition, inadequate clearance can cause the lens to become adhered to the eye. On the other hand, excessive clearance can increase the likelihood of introducing air bubbles when inserting the lens. Moreover, it has recently been shown that excessive clearance should be avoided in order to maximize oxygen

supply to the corneal surface.[57-59] Together, these findings have led to a slightly adapted classification scleral lens fitting. Compared to the original classification (Chapter 4), our new classification (Chapter 7 and 8) includes a somewhat lower degree of corneal clearance for "optimal" and "acceptable" grades (Table 3). In eyes that are prone to accumulating debris behind the lens, a smaller sagittal height should be chosen, as a large-volume cloudy fluid reservoir will impede the patient's visual acuity. In contrast, greater sagittal height may be required for eyes with possible progressive ectasia. Moreover, an irregularly shaped corneal surface can cause considerable differences in localized sagittal height, for example in the case of a tilted transplant. With mini-scleral lenses, a reduction in lens clearance (i.e., lens settling) can occur during the day, and this reduction can become more severe after several weeks of wear; this effect must be taken into account.[60,61]

Table 3. Scleral lens fitting characteristics.

	Grade -2 unacceptable	Grade -1 acceptable	Grade 0 optimal	Grade +1 acceptable	Grade +2 unacceptable
Central corneal clearance	Corneal contact	≤ 0.1 mm	0.1 - 0.3 mm	> 0.3 mm to ≤ 0.5 mm	> 0.5 mm
Limbal corneal clearance	Circumcorneal limbal contact	Circumcorneal < 0.05 mm	0.05 - 0.2 mm	Circumcorneal > 0.2 mm to ≤ 0.3 mm	Circumcorneal > 0.3 mm
Scleral (haptic) fit	Circumcorneal blanching	Segmented/ slight blanching	Scleral alignment	Slightly increased edge clearance	Increased edge clearance, with possible trapped air bubbles
Lens movement (push-up test)	Lens suction	Reduced	Gentle	Increased	Excessive

Scleral lens care and handling

Providing the patient with careful instructions regarding scleral lens care and handling is an essential part of the scleral lens fitting procedure in order to minimize complications.

Gas-permeable scleral contact lenses can be cleaned, wetted, and stored using a standard rigid RGP lens solution system. Alcohol-based cleaners are generally preferred due to their effectiveness at removing lipid and mucus deposits, as well as their ability to optimize wettability of the lens surface. Peroxide-based systems and/or weekly or monthly cleaning using a two-component intensive cleaner (Progent, Menicon Co. Ltd., Nagoya, Japan) that contains sodium hypochlorite and potassium bromide can effectively prevent the accumulation of proteins.

During the adaptation phase, wearing time should be extended gradually, and the patient should be monitored closely. A certain amount of eye redness and awareness of the lens' presence is to be expected while the eye adapts to the presence of the scleral lens.

Properties of scleral lenses

The properties that help make modern scleral lenses both suitable and successful for several indications have been well documented.[1,2,50] Table 4 summarizes the properties of scleral lenses.

Table 4. Properties of scleral lenses.

Advantages of scleral lenses
Stable fit irrespective of corneal topography
No contact with the cornea; no mechanical stress on the cornea
Optical correction of an irregular corneal shape
Continuous hydration of the ocular surface
Mechanical protection of the cornea against shear forces induced by eyelid movement
High refractive power is possible
Excellent positional stability on the eye[a]
Easy to find if dropped; difficult to dislodge from the eye
Foreign bodies are extremely rare
Robust and stable materials (suitable for elderly and/or less dexterous patients)
Minimal lid sensation (so tolerated well by patients)
Disadvantages of scleral lenses
The fitting procedure is relatively complicated
Handling the lenses has a long learning curve
Possibly psychological resistance to the lens' large size
Using only one lens can cause a difference in the aperture between the two eyes

[a] This outcome is discussed in Chapter 3

Complications associated with scleral lenses

The complications associated with scleral lenses can be categorized as either severe or non-severe complications (Table 5).

Table 5. Complications associated with scleral lenses.

Severe complications
Risk of microbial keratitis associated with the following factors: poor compliance, epithelial defects, immunosuppressive therapy, and extended wear
Incidental scleral lens–induced inflammatory response
Non-severe complications
Hypoxia
Slight change in corneal thickness, shape and power
Deposits on the lens surface and/or poor wettability
Debris in the fluid reservoir (e.g., lens fogging)
Loose conjunctival tissue
Tight lens adherence (i.e., suction)

The precise prevalence of severe complications among scleral lens users has not been systematically investigated in literature. However, recent reviews by van der Worp[1] and Schornack[2] found only a limited number of complications, mainly microbial keratitis. Although scleral lenses are often used to minimize inflammatory responses, scleral lens–induced inflammatory responses (e.g., corneal infiltrates) have been noted incidentally and have been attributed to a lack of tear exchange behind a scleral lens and/or solution-related toxicity.[50] Poor patient compliance,[7,62] epithelial defects,[3,10,12,63] immunosuppressive therapy,[12,63] and extended lens wear[3,10] have all been reported as possible causes of microbial keratitis associated with scleral lens wear. In contrast, wearing scleral lenses on an extended wear basis can be effective at promoting the healing of persistent corneal epithelial defects, for example in eyes that fail to heal in response to other therapeutic measures.[10,64] Moreover, it can be difficult to determine whether these complications were indeed due to scleral lens wear or were simply a manifestation of an underlying disease.[2]

Although infectious keratitis is not specifically seen with scleral lens users, as with other contact lenses, the practitioner should ensure that the patient is fully capable of complying with the lens care regime in order to minimize risk factors. It is important to educate the patient thoroughly with respect to hygiene, lens care, and the signs associated with infection. This approach is particularly important in patients with diseased corneas, as they can be more susceptible to damage. Furthermore, the effects of scleral lenses on ocular physiology (for example, the development of hypoxia) should be minimized.

Several studies have been published regarding the possible effects of scleral lenses on corneal physiology. Based on clinical reports, it appears that the principal serious

complication of the past—corneal edema—was largely solved by the introduction of high-gas-permeable materials. Kok and Visser[8] found that normal corneal physiology was maintained with high-oxygen-permeable scleral lens wear. Pullum and Stapleton[65] reported that the degree of central corneal swelling is less than 3% in patients who use scleral lenses made of a 115-Dk material. In addition, Compan et al.[58] found that subjects who were fitted with scleral lenses made of a 100-Dk material and with a central clearance of 150 or 350 microns had corneal swelling of 1.6% and 3.9% for the thinner and thicker fluid reservoirs, respectively, after three hours of wearing time. Although these degrees of swelling are within the physiological range of swelling that can occur overnight (i.e., when the eyes are closed), which can reach 4.5–5.5%,[66,67] it should be noted that hypoxia responses can differ among individual patients, particularly in the compromised eye. The recommendations made by Compan et al.,[58] to restrict hypoxia-induced swelling by using the highest Dk materials available and by minimizing both lens thickness and the fluid reservoir between the lens and cornea, are consistent with other studies by Michaud et al.[57] and Jaynes et al.[59] regarding scleral lens–induced corneal swelling. Particular attention should be given to eyes with compromised corneal endothelial function (e.g., in corneal transplants with a low endothelial cell count), as the hypoxic effect induced by scleral lenses can increase corneal swelling.

Bergmanson et al.[68] noted that hypoxia induced by wearing scleral lenses made from modern high-Dk materials has not been demonstrated sufficiently, citing the relative paucity of published clinical observations with respect to signs of corneal swelling. Rather, the authors propose that a number of factors can influence oxygen delivery; one such factor is the exchange between the fluid reservoir and tears peripheral to the lens. In contrast, Bergmanson et al.[68] refer to a theory proposed by Irving Fatt, who suggested that a scleral lens made of 100-Dk material can provide more than sufficient oxygen to the cornea; Fatt based this theory on the premise that oxygen that flows through the lens—and thus directly onto the cornea—should be considered, as there is no need for oxygen exchange around the perimeter of the lens. Future research might reveal the factors that influence oxygen delivery to the cornea while wearing a scleral lens.

Vincent et al.[56] studied healthy eyes and concluded that the short-term use of mini-scleral lenses does not induce significant corneal edema, although it slightly influences corneal shape and power by flattening the anterior corneal surface; moreover, rebound thinning and flattening of the posterior surface was observed following the recovery period.

Some complications associated with scleral lenses reduce visual clarity; these complications include deposits on the lens surface (Figure 11), poor lens surface wettability (Figure 11), and debris in the fluid reservoir (e.g., lens fogging; see Figure 12). Although the prevalence

of these complications appears to be mutual exclusive,[69] they are more common among patients with atopic conditions and/or ocular surface diseases. Problems such as surface deposits and lens wettability can be minimized by treating the existing eyelid disease or giant papillary conjunctivitis, cleaning the lenses with a suitable cleaning agent, rubbing the lens surface with a conditioning solution, using a plasma-treated lens material, or using non-preserved lubricants and/or protein-removing eye drops[70] (Clens 100, Alcon, Fort Worth, TX, USA) during lens wear.

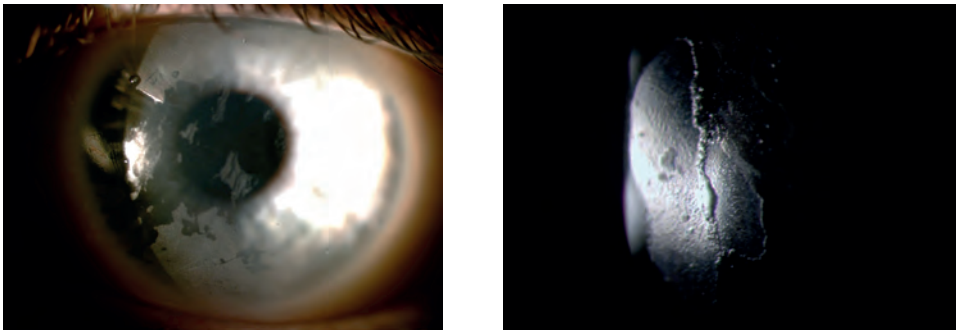

Figure 11. Deposits and poor lens surface wettability.
Left: protein deposits on the scleral lens surface. Right: mucus deposits and poor lens surface wettability.

Figure 12. Debris in the fluid reservoir.
Left: mucus-like debris. Right: particulate debris.

The specific cause of lens fogging is poorly understood, but one possible cause is a lipid substance (rather than the initially hypothesized compound mucin).[69,71] The fluid forces associated with scleral lens pressure that occurs during blinking are likely responsible for introducing debris from the peripheral region of the scleral lens into the fluid reservoir.[71] Strategies to minimize lens fogging include fitting the scleral lens with minimal clearance,[69,71] periodically removing and cleaning the lenses,[8,38,69,71] rinsing the eyes with non-preserved

saline or a rinsing solution that contains sodium hyaluronate (Vismed wash, TRB Chemedica AG, Geneva, Switzerland) before inserting the lenses, reinserting the lenses shortly after the first insertion,[69] inserting the lenses with a high-viscosity non-preserved solution such as artificial tears,[69,71,72] and modifying the lens fit by improving scleral zone alignment in order to prevent debris from getting under the lens.[50,71,72]

Conjunctival prolapse (Figure 13) typically occurs when the eye's conjunctival tissue is loose or baggy,[45] and it can arise from negative pressure forces beneath the lens. These conjunctival folds are usually considered to be relatively benign, although a case in which the prolapsed conjunctiva was anchored to the underlying corneal surface was described by Caroline and André.[73] Moreover, neovascularization can occur in regions in which the folds have persisted for long periods of time.[45]

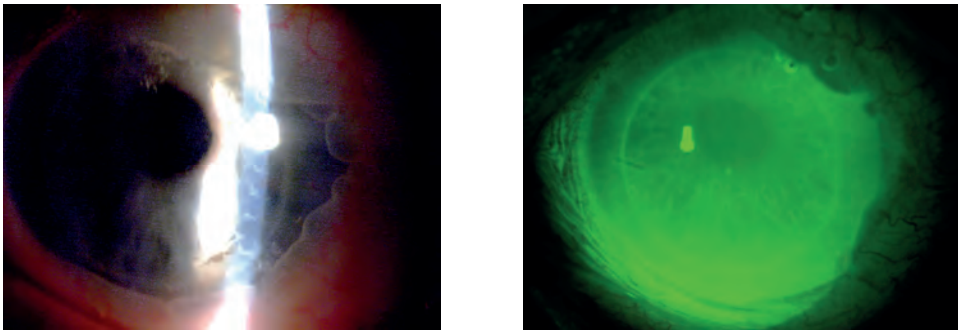

Figure 13. Conjunctival prolapse.
Left: conjunctival prolapse underneath a scleral lens. Right: the same eye; the fluid reservoir was stained with fluorescein.

A phenomenon specifically associated with scleral lens wear is tight lens adherence (i.e., lens suction), which is more common in dry eye conditions.[8,50] Lens suction can lead to limited tolerance and can have a significant impact on ocular physiology; therefore, this phenomenon should be minimized as much as possible. The signs and symptoms of lens suction include discomfort, bulbar conjunctival injection, conjunctival and/or corneal edema, superficial corneal staining, increased lens awareness, and cloudy vision. Lens suction can be minimized by using a steeper sagittal depth (if the corneal clearance appears to be inadequate), by optimizing the scleral zone fit (by reducing the lens diameter or by refitting with a back-surface toric design lens), or by inserting the lenses with non-preserved lubricating eye drops containing hyaluronate acid, and using these drops during wear. In addition, lens handling can be improved by instructing the patient to make horizontal eye movements with the eyes closed in order to facilitate tear exchange, thereby reversing the

negative pressure underneath the lens. Care should also be taken with respect to lens removal; the negative pressure underneath the lens can be reversed by lifting the lens edge with a suction holder, which is placed near the lens edge after instilling rewetting drops.

The following complications can arise due to poor fitting: bulbar redness and conjunctival blanching due to a tight-fitting scleral zone; entrapped air bubbles due to a loose-fitting scleral zone; localized limbal edema due to mechanical stress induced by lens adhesion, entrapped air bubbles, or insufficient limbal clearance; and corneal staining due to lens contact with the cornea or an entrapped, immobile air bubble. Corneal staining can also result from an allergic or toxic reaction to compounds in the eye care products or from an improperly inserted scleral lens. Furthermore, diplopia can develop due to air bubbles, an excess fluid reservoir, prismatic corneal clearance, or a decentered lens fit.

Indications for scleral lenses

Many researchers have examined the indications for scleral lenses (Table 6).[1,2,50] One of the primary goals in fitting scleral lenses is to achieve visual rehabilitation with improved lens performance in cases in which the patient is unable to wear traditional corneal lenses (e.g., poor centration, instability, or low tolerability). Corneal irregularity is the most common indication for scleral lens fitting;[3-8,74-80] however, scleral lenses have also been used to manage patients with ocular surface disease, in which the scleral lenses moisten and protect the ocular surface.[3,8-12,29,64,70,77,81-84] Moreover, scleral lenses may be used in patients with higher-power corrective errors because the design of the lens can have high refractive power. Other indications include eyelid defects, for which a scleral lens can provide good protection of the corneal surface. In ptosis, the lens is used to keep the eyelid retracted.

Scleral lenses can be beneficial in patients who are engaged in water sports, contact sports, or activities in dry and/or dusty environments, particularly because scleral lenses are not easily lost and because foreign bodies are rarely trapped under the lens.

Hand-painted prosthetic scleral lenses can be used for cosmetic purposes in eyes that do not need oxygenation through the lens (e.g., in bulbous atrophy), as these lenses are composed of PMMA.[85]

The indications for scleral lenses are listed in Table 6, and some of the more common indications are illustrated in Figures 14-17.

Table 6. Indications for scleral lenses

Indication	Sub-category
Corneal irregularity	
Primary corneal ectasia	Keratoconus (including keratoconus managed with intrastromal ring implants and corneal crosslinking [CXL]) Keratoglobus Pellucid marginal degeneration (PMD)
Post-keratoplasty	Penetrating keratoplasty Anterior lamellar keratoplasty
Corneal scarring	Herpes simplex keratitis Other infectious keratitis Trauma Some stromal corneal dystrophies
Post-refractive surgery	Radial keratotomy (RK) Photorefractive keratectomy (PRK) Laser-assisted in situ keratomileusis (LASIK) Laser-assisted subepithelial keratectomy (LASEK)
Following surgery (other than keratoplasty)	Pterygium resection
Ocular surface disease	
Keratitis sicca	Sjögren's syndrome Neurotrophic keratopathy Following irradiation
Exposure keratopathy	Acoustic neuroma resection Nerve palsies Exophthalmos/Grave's ophthalmopathy Following eyelid surgery
Graft-versus-host disease	
Corneal degeneration	Salzmann's nodular degeneration Terrien's marginal degeneration
Cicatrizing conjunctivitis	Stevens-Johnson syndrome Ocular cicatricial pemphigoid
Recurrent epithelial corneal defects	Epithelial and subepithelial corneal dystrophies (e.g. epithelial basement membrane dystrophy [EBMD])[86]
Congenital corneal hypoanesthesia	
Vernal keratopathy	
Atopic keratoconjunctivitis	
Symblepharon	
Refractive	
High refractive error	High hyperopia High myopia Aphakia
Anisometropia	
Severe astigmatism	
Cornea plana	
Eye lid disorders	
Ptosis	
Trichiasis	
Ectropion	
Entropion	
Eyelid coloboma	
Miscellaneous indications	
Bulbous atrophy	
Sports	Water sports Contact sports
Exposure to dusty environments	

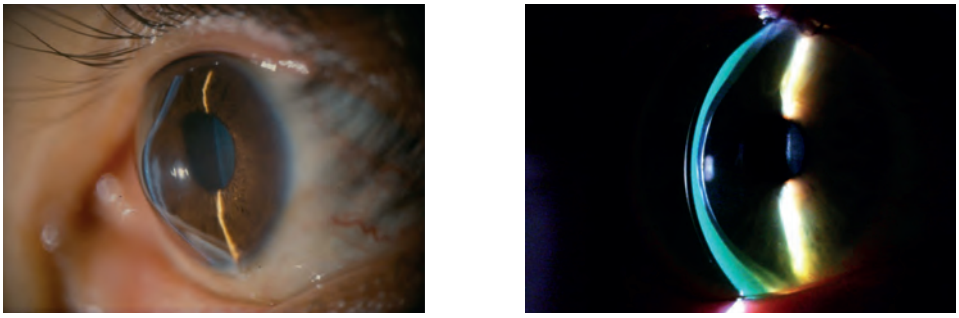

Figure 14. Keratoconus.
Left: keratoconus. Right: keratoconus corrected with a scleral lens.

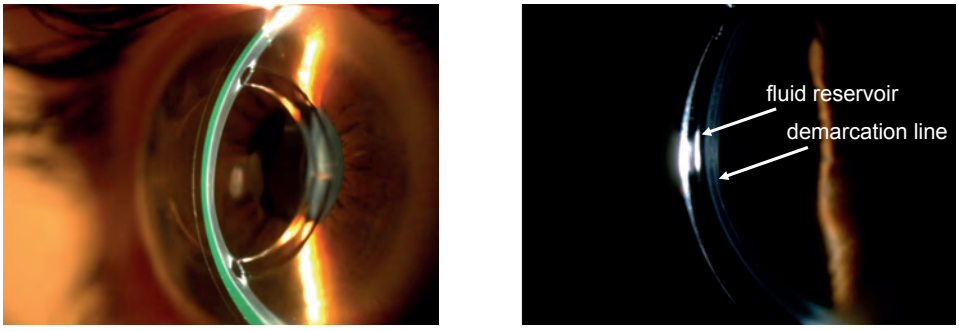

Figure 15. Keratoconus after treatment.
Left: intrastromal ring implants in keratoconus corrected with a scleral lens. Right: after corneal crosslinking (CXL) corrected with a scleral lens.

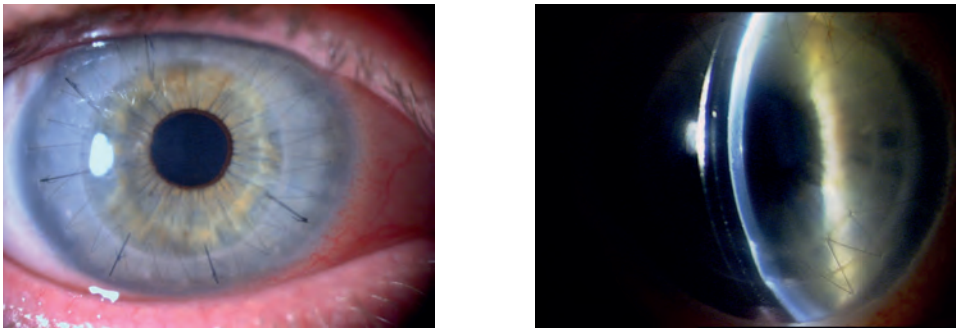

Figure 16. Penetrating keratoplasty.
Left: penetrating keratoplasty. Right: scleral lens after penetrating keratoplasty.

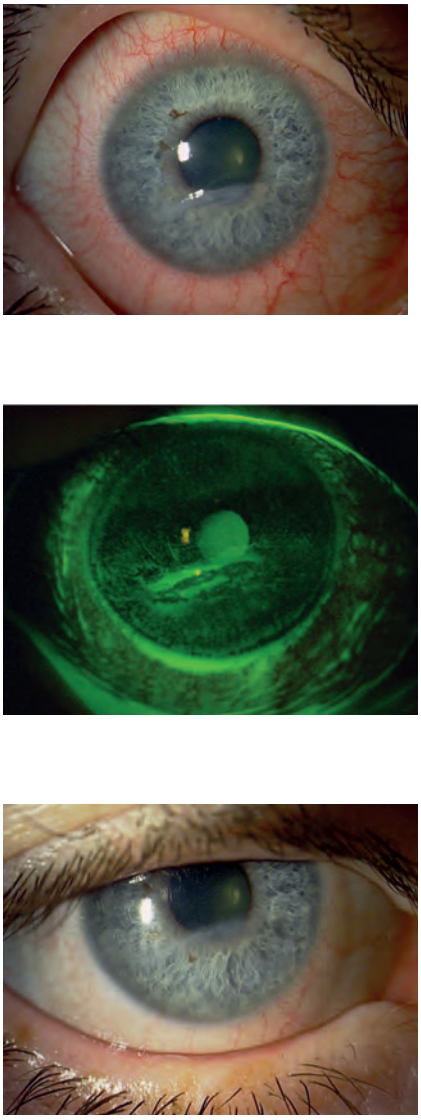

Figure 17. Exposure keratitis.
Top: exposure keratitis following acoustic neuroma resection. Middle: same eye stained with fluorescein. Bottom: improvement in the eye condition after two weeks of scleral lens wear.

Outline of the thesis

This thesis evaluates the present status and performance of modern scleral lenses, including two innovative types (i.e., back-surface toric and tangential scleral lenses), and examines the effect of these lenses on corneal physiology and ocular tolerance in patients who underwent corneal crosslinking (CXL).

Chapter 1 presents a brief overview of the history, fundamental properties (e.g., the nomenclature, design, materials, fitting, advantages and disadvantages), complications, and indications associated with scleral lenses.

Chapter 2 evaluates the objective and subjective performance of a variety of medical contact lenses fitted for a broad range of clinical indications using a lens selection algorithm. This chapter also describes the role of scleral lenses among other types of contact lenses.

Chapter 3 examines the positional stability of back-surface toric scleral lenses on the eye and changes in patient satisfaction with respect to comfort and wearing time.

Chapter 4 discusses the indications for scleral lenses and their clinical performance.

Chapter 5 describes the subjective performance of scleral lenses. Moreover, the added value of back-surface toric scleral lenses is discussed with respect to comfort, visual quality, and overall satisfaction compared to back-surface spherical scleral lenses.

Chapter 6 evaluates the clinical results of a newly developed scleral lens design with a bitangential (nonrotationally symmetrical) periphery.

Chapter 7 presents the change in scleral lens tolerance and fitting aspects before and one year after CXL in progressive keratoconus.

Chapter 8 discusses the influence of scleral lens wear on corneal curvature and/or pachymetry.

Chapter 9 provides the summary, conclusions, closing remarks and future perspectives of this thesis in English.

Chapter 10 contains Dutch versions of the summary and conclusions.

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Chapter 2

Objective and subjective evaluation of the performance of medical contact lenses fitted using a contact lens selection algorithm

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Submitted for publication

Abstract

Purpose: To evaluate the objective and subjective performance of medical contact lenses (CLs) fitted for a broad range of clinical indications using a lens selection algorithm.

Design: Prospective observational study.

Subjects: A total of 281 eyes were evaluated from 281 patients who visited the contact lens service at a tertiary academic clinic (University Medical Center Utrecht, the Netherlands) in the period from August 2014 through October 2014.

Methods: We obtained each patient's medical history, CL history, and visual acuity; in addition, patients completed a questionnaire.

Main outcome measures: Clinical indications for CL wear; CL type; change in corrected distance visual acuity (CDVA) with CL use; CL wearing duration; CL wearing time; subjective measurements on a visual analog scale (VAS) questionnaire (score range: 0-100); and the effectiveness of the lens selection algorithm.

Results: The most common indications were keratoconus (25%), dry eye disease (23%), and keratoplasty (20%); the most common CL types were scleral lenses (53%) and soft lenses (either conventional soft lenses or silicone hydrogel lenses; 35%). The use of CLs significantly improved CDVA compared to the use of spectacles (the median change was -0.15 logarithm of the minimal angle of resolution (logMAR) (range: 1.00 to -2.10; $P<0.001$)). Daily-wear CLs were worn by 77% of patients for a median of 15 hours/day (range: 5-18 hours), 7 days/week (range: 1-7 days); the remaining 33% of patients wore their lenses continuously. With respect to the questionnaire, the patients generally reported high scores for comfort, visual quality, lens handling, and overall satisfaction, with similar results between the scleral lens and soft lens groups. The lens selection algorithm was found to be generally effective, as indicated by an overall satisfaction rating >70 in 81% of patients.

Conclusions: CLs fitted using the lens selection algorithm yield satisfactory clinical results, including improved visual acuity, satisfactory wearing time, and satisfactory overall subjective performance. Moreover, subjective performance was similar between scleral lens users and soft lens users. This study underscores the importance of using scleral lenses and the need for offering a variety of CL types in tertiary eye clinics.

Introduction

To treat a wide range of ocular diseases, modern-day eye-care practitioners have a growing arsenal of medical contact lenses (CLs). The primary optical indication for fitting a patient with medical CLs is to improve visual acuity in cases of high refractive error and/or irregular astigmatism;[1] less common indications include anisometropia, nystagmus, and occlusion.[2] In a clinical setting, another important indication for CL use is for therapeutic purposes (e.g., in the case of a corneal bandage, in which the cornea is physically protected from the environment in order to improve hydration, promote corneal healing, and relieve pain).[3-10] Often, several effects are desired.[4,6] All of these applications have specific requirements with respect to the lenses' design and material. A wide variety of CL types are currently available, including conventional soft lenses, silicone hydrogel lenses, rigid gas-permeable (RGP) corneal lenses, scleral lenses, hybrid lenses, occlusive lenses, iris print lenses, filter lenses, piggyback systems, and scleral prosthetics. Tailoring a CL to adequately fit the patient's needs requires a trained eye-care practitioner.

Clinical applications for CLs have expanded due to improvements in the materials used (for example, more permeable lens materials)[3] and recent innovations in lens design, including custom-made specialized lenses,[11,12] and toric- and tangential scleral lens designs.[13-15] In turn, these developments have altered the prescription habits of eye-care practitioners. For example, the improved material properties of silicone hydrogels has led to a major shift from conventional soft lenses to silicone hydrogel lenses.[5,8] More interestingly, the increased availability of custom-designed contact lenses for patients with keratoconus or keratoplasty[11,16-20] has been accompanied by a large increase in the use of scleral lenses.[21-23] Scleral lenses play an important role in medical CL practice, particularly in cases in which other lens designs have suboptimal results, for example in the case of unstable lens fitting, poor tolerance, unsatisfactory visual improvement, and/or corneal bandage. However, the ability to fit scleral lenses requires specific skills and training. Another factor that has hampered the popularity of scleral lenses is prejudice with respect to poor handling of scleral lenses and a lack of comfort for the user. Recently, Van der Worp et al.[21] and Schornack[22] reviewed the outcomes of studies using scleral lenses, and several studies have evaluated the fitting of medical CLs in specific settings.[1,3,5,7,19,24] However, no overarching, evidence-based method for fitting the optimal CL type in more challenging clinical cases is currently available. In addition, the patients' subjective experiences based on these various treatment strategies also warrant attention.

Our goal was to evaluate the experiences of CL practitioners and patients in a large, tertiary clinic. Thus, we prospectively evaluated the effectiveness of a practical lens selection algorithm, and we examined the clinical outcomes and patient satisfaction in response to the strategies chosen. Importantly, the comprehensive lens selection algorithm enables practitioners to achieve desirable results.

Methods

In this prospective observational study, we included all consecutive patients who visited the Contact Lens service (Visser Contact Lens Practice) at the University Medical Center Utrecht from August 2014 through October 2014 for a follow-up for a medically indicated CL. The inclusion criteria were >18 years of age and CL use for >3 months prior to enrollment. The exclusion criteria were patients who came for an emergency visit or patients who were unable or unwilling to participate. Our institution's Ethics Review Board ruled that approval was not required for this study; however, all participating patients provided written informed consent. All procedures were performed in accordance with the Declaration of Helsinki and with local laws regarding research on human subjects.

During the study visit, the primary and secondary clinical indication for CL use, CL type, and CL history were recorded; in addition, the following data were obtained from the patients' medical history: the presence of allergies and/or eczema, the use of topical eye drops (e.g., lubricants, prophylactic antibiotics, steroids, glaucoma eye drops, anti-allergy eye drops, or other eye drops), and average CL wearing time. Best corrected distance visual acuity (CDVA) was measured as Snellen visual acuity both with (CL CDVA) and without (spectacle CDVA) CLs.

All patients were also instructed to complete a questionnaire covering the following four specific topics: lens comfort, visual quality, lens handling, and overall satisfaction with their lenses. Scores were obtained on a visual analog scale (VAS); the scores ranged from 0 (unacceptable performance) to 100 (excellent performance). This questionnaire was used in our previous studies, and approval for using it here was granted by the Research and Ethics Committee of the City University, London, United Kingdom.[25,26] Patients with a visual acuity score of <1/300 (i.e., <distinguish hand motion) did not complete the questions regarding visual quality; CVDA was also not evaluated in these patients. Patients with continuous-wear bandage lenses were omitted from the lens handling section of the questionnaire, as their lenses were replaced by our contact lens service; lens wearing time was also not determined in these patients.

Patients with continuous-wear CLs visited the practice every 4-6 weeks to either replace or clean their lenses, and they were prescribed prophylactic antibiotic eye drops (chloramphenicol 0.5%, minims BID; Bausch & Lomb). All other patients were monitored at an interval that met their specific clinical needs.

Contact lens selection

The selection of a specific CL type was based on the severity of the disorder and the presence of additional indications and/or other complicating factors.

Our CL selection algorithm was developed for two principal uses for medical CLs: irregular astigmatism and bandage (Figure 1). The grading of severe dry eye included grade IV and V based on the Oxford Index for staining and tear film break-up time.[30] A grade of mild, moderate, or advanced corneal irregularity was determined based on CL performance and acceptable visual quality: SiHy or RGP corneal trial lenses, which were fitted in accordance with the manufacturer's guidelines, were used to assess the effects of corneal irregularity. The grade "mild" refers to acceptable subjective visual quality with a SiHy lens; the grade "moderate" refers to unacceptable subjective visual quality with a SiHy lens and an acceptable lens fit with a RGP corneal lens; and the grade "advanced" refers to unacceptable subjective visual quality with a SiHy lens and an unacceptable lens fit with a RGP corneal lens. A grading system for irregular astigmatism (based on absolute values measured using corneal topography) was not applicable in this study, as the actual location of the corneal irregularity or cone (i.e., central or peripheral) can have a significant influence on CL fitting. For example, an advanced centrally located keratoconus might benefit from a RGP corneal lens, whereas a less advanced inferiorly located protrusion might impede the fitting of an RGP corneal lens, thus requiring a scleral lens.

Our approach to select the appropriate type of soft lens (including conventional soft lenses or silicone hydrogel lenses) is summarized in Figure 2. Indications beyond this scope (e.g., occlusion lenses, filter lenses, or cosmetic lenses) were not included in the lens selection algorithm, as these types of lenses are directly related to their specific indications. Medical refractive indications, including high refractive error (i.e., refractive error that exceeded +/-10 diopters [D]), aphakia, and anisometropia, were tailored to the individual patient's needs. The best-fitting CL material and design was prescribed to each individual patient based on the practitioner's judgment using trial lenses.

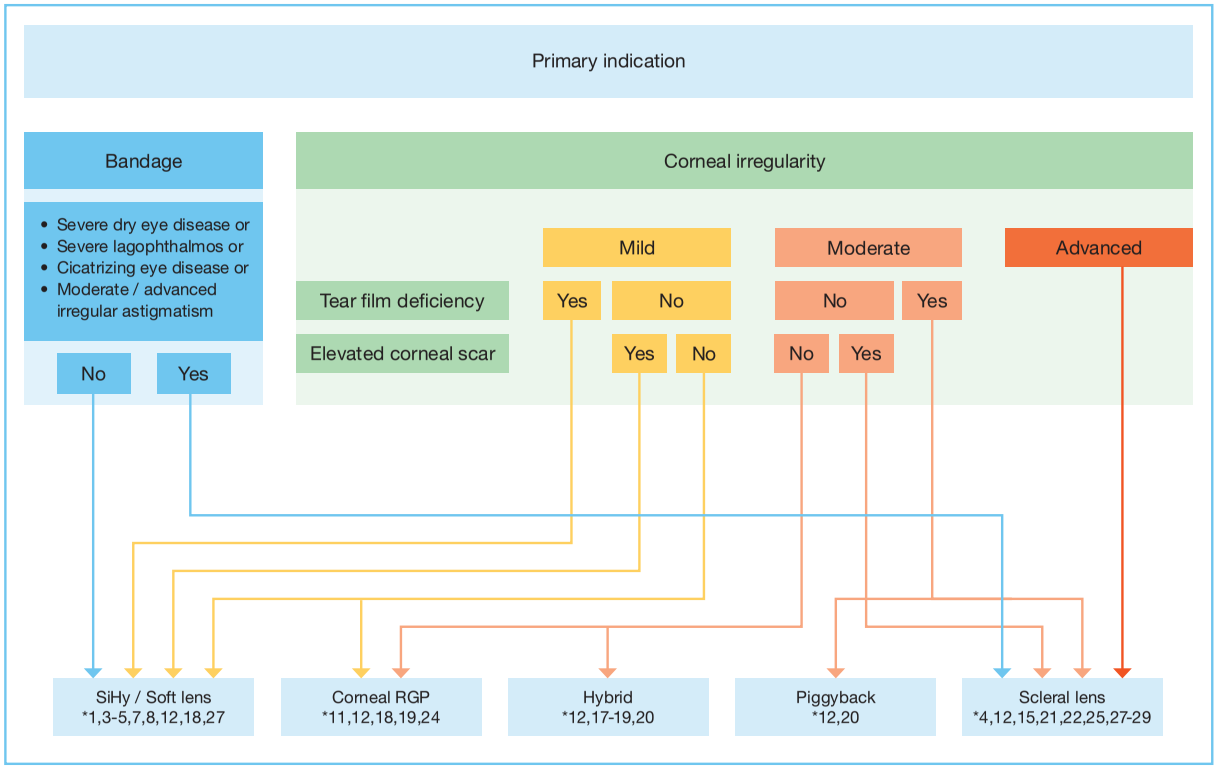

Figure 1. Contact lens selection algorithm.
A selection algorithm for selecting contact lenses for two principal medical uses: irregular astigmatism and bandage.
SiHy = silicone hydrogel; RGP = rigid gas-permeable.
* = references listed in the main reference list.
Mild corneal irregularity = acceptable subjective visual quality with SiHy; Moderate corneal irregularity = unacceptable subjective visual quality with SiHy, acceptable lens fit with RGP corneal; Advanced corneal irregularity = unacceptable subjective visual quality with SiHy, no acceptable lens fit with RGP corneal.
Note: The grading of severe dry eye included grade IV and V based on the Oxford Index for staining and tear film break-up time.[30] SiHy or RGP corneal trial lenses were used to determine the grade of “mild”, “moderate”, or “advanced” corneal irregularity. A grading system for irregular astigmatism based on absolute values measured using corneal topography was not applicable in this study.

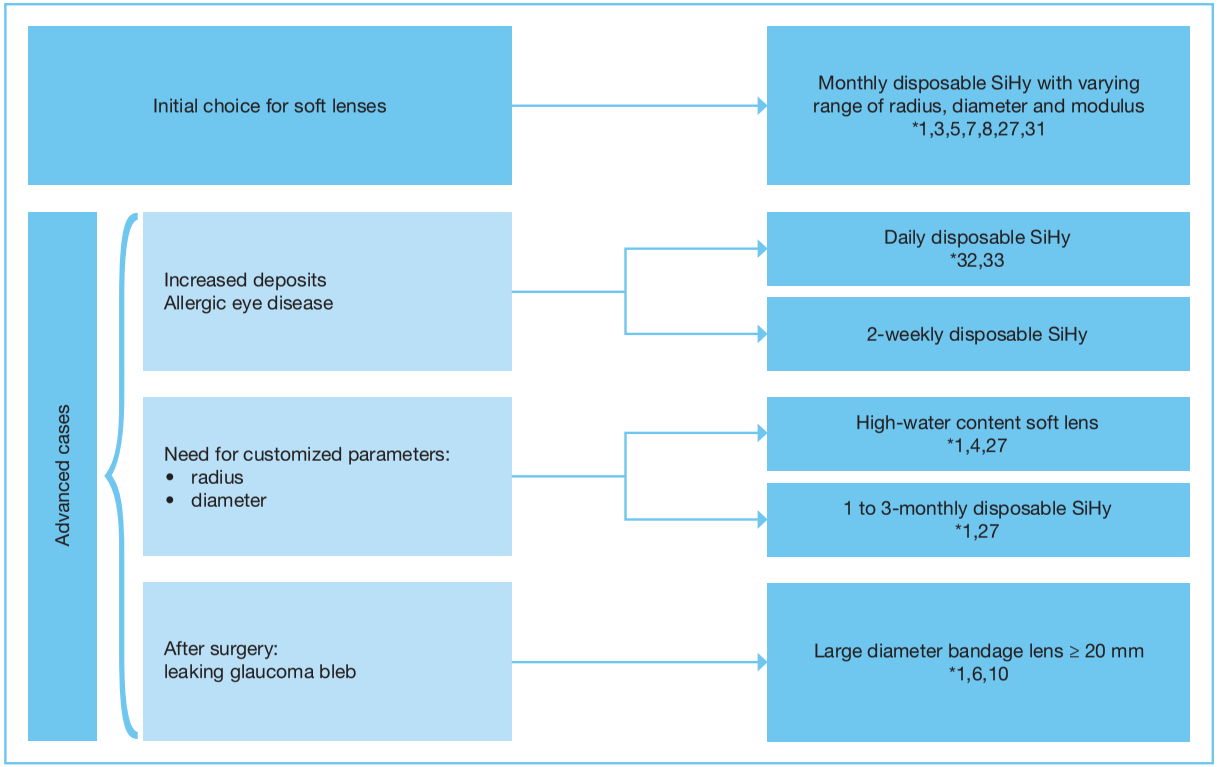

Figure 2. Initial and advanced selection of soft lenses for medical use.
Flowchart for the initial and advanced selection of soft lenses (conventional soft or SiHy lenses) for medical use.
SiHy = silicone hydrogel.
* = references listed in the main reference list.

A detailed description of the scleral lens fitting protocol has been described previously.[13,15,25] In brief, fitting was based on the landing of the scleral lens on the sclera and vaulting of the lens over the cornea and limbus. Ideal scleral lens fitting has a well-balanced haptic bearing, gentle movement of the lens with the push-up test, and adequate corneal and limbal clearance. All other lenses were fitted in accordance with the applicable manufacturers' protocols.

Statistics

One eye in each subject was selected at random using an autonomous software tool (nQuery Advisor, version 7.0, Statistical Solutions, Cork, Ireland). All Snellen visual acuity values were converted to logarithm of the minimal angle of resolution (logMAR) values for statistical calculations.

All variables were tested for normal distribution using the Kolmogorov-Smirnov test. The only variable that was found to be distributed normally was patient age. For non-normally distributed paired data, the Wilcoxon signed rank test was used. Differences between groups were analyzed using the non-parametric Kruskal-Wallis test (for continuous outcomes), the Fisher's exact test (for categorical outcomes), or ANOVA (age). With the exception of patient age (which is reported as the mean and standard deviation), all summary data are reported as the median and range. Subgroup analyses were performed on the following stratified data: primary clinical indication (keratoconus, dry eye disease, or post-keratoplasty) and primary CL type (scleral lens or soft lens). Differences with a *P*-value <0.05 were considered statistically significant. All statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY,US).

Results

This study included 281 eyes from 281 patients; 160 patients were female (57%), and 142 eyes were right eyes (51%). The mean age of the patient cohort was 55 ± 17 years (range: 18 to 93 years). Slightly more than half of the patients (n=158) wore CLs in both eyes, whereas 63 and 60 patients wore a single lens in the right or left eye, respectively.

Thirty-four percent of patients presented with some form of allergy, and 15% had eczema. Sixty-one percent of patients used topical eye drops; among the patients who used eye drops, 47% used a lubricant, 24% used prophylactic antibiotics, 15% used steroids, 7% used glaucoma eye drops, 5% used anti-allergy eye drops, and 2% did not specify the type of eye drops used.

Clinical indications

The three most common clinical indications in our study cohort were keratoconus (in 25% of cases), dry eye disease (23%), and keratoplasty (20%). The primary clinical indications and the CLs applied are summarized in Table 1. The results of these three main indication groups were further analyzed, and the demographic data are summarized in Table 2.

In total, 26 of the 281 eyes (9%) had a secondary clinical indication for CL fitting; these indications included dry eye disease (n=5), aniridia (n=4), decompensated cornea (n=3), corneal scarring after trauma (n=3), anisometropia (n=2), aphakia (n=2), high refractive error (exceeding +/-10 D; n=1), corneal scarring after infection (n=1), keratoplasty (n=1), corneal dystrophy (n=1), recurrent erosions (n=1), trichiasis (n=1), and white pupil secondary to cataract (n=1).

All corneal transplants, with the exception of one anterior lamellar keratoplasty, were perforating grafting procedures. Indications for transplant surgery included keratoconus (n=24), Fuchs endothelial dystrophy (n=18, all of which were performed in the pre-endothelial keratoplasty era), post-infectious keratitis scar (n=8), cornea decompensation (n=4), and unspecified corneal dystrophy (n=1).

The most common primary clinical reasons for applying CLs were to improve visual acuity (in 63% of cases) and as a bandage (34%). A small number of patients were fitted with CLs for cosmetic purposes (n=4), occlusion (n=3), or for improved contrast vision (n=1).

Table 1. Clinical indications and contact lens type.

Indication	No. of eyes, n (%)	Contact lens type						
		Scleral	Soft	RGP Corneal	Occlusive	Iris	Filter	Other[a]
Keratoconus	**71 (25)**	**60**	**4**	**6**	**0**	**0**	**0**	**1**
Dry eye disease	**66 (23)**	**14**	**52**	**0**	**0**	**0**	**0**	**0**
Keratitis sicca	60	10	50	-	-	-	-	-
Keratitis lagophthalmos	6	4	2	-	-	-	-	-
Keratoplasty	**55 (20)**	**51**	**1**	**2**	**0**	**0**	**0**	**1**
Corneal scar	**25 (9)**	**17**	**2**	**4**	**1**	**0**	**0**	**1**
After herpes simplex keratitis	9	6	2	1	-	-	-	-
After other infectious keratitis	13	9	-	3	1	-	-	-
After trauma	3	2	-	-	-	-	-	1
Refractive	**19 (7)**	**3**	**11**	**2**	**0**	**1**	**2**	**0**
High refractive error >+/-10 D	9	3	4	1	-	1	-	-
Aphakia	6	-	4	-	-	-	2	-
Anisometropia	4	-	3	1	-	-		-
Cornea decompensation	**17 (6)**	0	**14**	**0**	**0**	**1**	**2**	**0**
Corneal erosions	**12 (4)**	**0**	**12**	**0**	**0**	**0**	**0**	**0**
Other irregular astigmatism	**5 (2)**	**3**	**0**	**2**	**0**	**0**	**0**	**0**
After surgery (other than keratoplasty)	4	3	-	1	-	-	-	-
Unknown cause	1	-	-	1	-	-	-	-
Miscellaneous indications	**11 (4)**	**0**	**3**	**1**	**4**	**2**	**0**	**1**
Binocular diplopia	3	-	-	-	3	-	-	-
Trichiasis	2	-	2	-	-	-	-	-
Aniridia	1	-	-	-	-	1	-	-
Entropion	1	-	1	-	-	-	-	-
Bulbus atrophy	1	-	-	-	-	-	-	1
Iris atrophy	1	-	-	-	-	1	-	-
Nystagmus	1	-	-	1	-	-	-	-
White pupil	1	-	-	-	1	-	-	-
Total no. of eyes, n (%)	**281 (100)**	**148 (53)**	**99 (35)**	**17 (6)**	**5 (2)**	**4 (1)**	**4 (1)**	**4 (1)**

D = Diopter; RGP = rigid gas-permeable.

[a] Other = a piggyback system for keratoconus (n=1), a hybrid lens for keratoplasty (n=1), a tinted soft keratoconus lens for a corneal scar after trauma (n=1), and a prosthetic scleral lens for bulbous atrophy (n=1).

Table 2. Main groups of clinical indications: general data.

Indication group	No. of eyes	Mean age, years (range)	Gender, % male/female	Allergy, n (%)	Eczema, n (%)
Keratoconus	71	47 (21-74)	47/54	33 (46)	19 (27)
Dry eye disease	66	59 (20-87)	24/76	20 (30)	10 (15)
Keratoplasty	55	63 (27-90)	51/49	19 (35)	5 (9)
Difference between the three indication groups, *P*-value		<0.001[a]	0.004[b]	0.13[b]	0.03[b]

[a] Analysis of variance (ANOVA) test.
[b] Fisher's exact test.

Contact lens types

The types of CLs used by the study cohort are summarized in Table 1. The most commonly used CLs were scleral lenses (in 53% of cases) and soft lenses (either conventional soft lenses or silicone hydrogel lenses; 35%); the results of these two groups were analyzed further.

The scleral lens group contained patients who used mini-scleral lenses (15-18 mm in diameter; n=20 patients) or regular scleral lenses (18-22 mm in diameter, n=128 patients). The most popular soft lenses were monthly disposable silicone hydrogels (n=65); the remaining soft lenses were 3-month disposable silicone hydrogels (n=13), daily disposable silicone hydrogels (n=7), daily disposable soft lenses (n=4), large-diameter soft lenses (n=4), 2-week disposable silicone hydrogels (n=2), 3-month disposable soft lenses (n=2), monthly disposable soft lenses (n=1), and aphakia soft lenses (n=1).

The RGP corneal lens designs included a standard corneal design (n=8), a keratoconus design (n=6), and a keratoplasty design (n=3).

Visual acuity outcomes

There was a significant improvement in median logMAR CL CDVA (-0.15; range: 1.00 to -2.10) compared to the median logMAR spectacle CDVA (P<0.001). The visual outcomes for the total cohort, the major clinical indication subgroups, and the lens subgroups are summarized in Table 3. CDVA improvement by CL wear differed significantly between the major indication groups (P<0.001, Kruskal-Wallis test); specifically, CL CDVA improved significantly more in the patients with keratoconus and keratoplasty compared with the patients with dry eye disease. Furthermore, users of scleral lenses had significantly more CDVA improvement than users of soft lenses (P<0.001, Kruskal-Wallis test).

Eighteen of the 281 eyes (6%) had visual acuity that was <1/300 (i.e., <distinguish hand motion).

Table 3. Spectacle and contact lens CDVA.

Indication or lens group	No. of eyes CDVA ≥1/300,[a] n (%)	Spectacle CDVA	Contact lens CDVA	CDVA difference	*P*-value[b]
Total group	**263 (94)**				
LogMAR		0.30 (2.52 – -0.10)	0.10 (2.52 – -0.20)	-0.15 (1.00 – -2.10)	<0.001
Snellen equivalent		20/40	20/25	N/A	N/A
Keratoconus	**71 (100)**				
LogMAR		0.40 (2.52 – -0.10)	0.10 (1.00 – -0.10)	-0.30 (0.12 – -1.70)	<0.001
Snellen equivalent		20/50	20/25	N/A	N/A
Dry eye disease	**64 (97)**				
LogMAR		0.10 (1.30 – -0.10)	0.07 (0.80 – -0.20)	0.00 (0.14 – -1.13)	=0.007
Snellen equivalent		20/25	20/24	N/A	N/A
Keratoplasty	**55 (100)**				
LogMAR		0.42 (2.52 – 0.00)	0.05 (2.22 – -0.10)	-0.32 (0.15 – -2.10)	<0.001
Snellen equivalent		20/53	20/22	N/A	N/A
Scleral lenses	**148 (100)**				
LogMAR		0.40 (2.52 – -0.10)	0.05 (1.30 – -0.20)	-0.30 (0.15 – -2.10)	<0.001
Snellen equivalent		20/50	20/22	N/A	N/A
Soft lenses	**88 (89)**				
LogMAR		0.19 (2.52 – -0.10)	0.12 (2.52 – -0.10)	0.00 (0.14 – -1.40)	=0.032
Snellen equivalent		20/31	20/27	N/A	N/A

CDVA = corrected distance visual acuity; LogMAR = logarithm of the minimal angle of resolution; CDVA outcomes are presented as median (range); N/A = not applicable.
[a] ≥Distinguish hand motion.
[b] Wilcoxon signed ranks test.

Wearing time and duration of CL use

Daily-wear contact lenses were worn by 77% of patients, with a median of 15 hours per day (range: 5 to 18 hours) and a median of 7 days per week (range: 1 to 7 days). The remaining 23% of patients wore their lenses continuously. The wearing time data in the clinical indication and lens type subgroups are summarized in Table 4.

In our cohort, 96% of patients wore their CLs >8 hours per day. Among the patients who wore their CLs <8 hours per day, 5 used scleral lenses, 2 used occlusive lenses, 1 used a soft lens, 1 used a tinted soft keratoconus lens, 1 used a filter lens, and 1 used a prosthetic scleral lens.

The median duration of wearing the current CL type was 6 years (range: 3 months to 39 years), and median CL wear duration in general was 11 years (range: 4 months to 53 years). Fifty-eight percent of patients had used a different CL type prior to the study.

Table 4. Wearing time per day and per week.

Indication or lens group	No. of eyes daily wear, n (%)	Median wearing time per day, hours (range)	Median wearing time per week, days (range)
Total group	216 (77)	15 (5-18)	7 (1-7)
Keratoconus	71 (100)	15 (5-18)	7 (4-7)
Dry eye disease	29 (44)	16 (6-16)	7 (2-7)
Keratoplasty	54 (98)	15 (6-18)	7 (2-7)
Scleral	148 (100)	15 (5-18)	7 (2-7)
Soft	34 (34)	16 (7-17)	7 (4-7)

Subjective performance

Median VAS outcome for the entire cohort was 84 for the topic of comfort (range: 14 to 100), 76 for visual quality (range: 4 to 100), 86 for lens handling (range: 15 to 100), and 85 for overall satisfaction (range: 7 to 100). The outcome of the patient questionnaire for all patient subgroups is summarized in Table 5.

The three clinical indication groups did not differ significantly with respect to comfort (P=0.16), visual quality (P=0.14), lens handling (P=0.15), or overall satisfaction (P= 0.43; Kruskal-Wallis test).

Scleral lens users did not differ significantly from soft lens users with respect to comfort (P=0.29), lens handling (P=0.21), or overall satisfaction (P=0.21, Kruskal-Wallis test). However, with respect to subjective visual quality, scleral lens users differed significantly from soft lens users (median VAS scores were 77.5 and 75, respectively; P=0.009, Kruskal-Wallis test).

Five percent of patients scored <50 in the comfort topic; 3 used scleral lenses, 6 used soft lenses, 2 used corneal lenses, 2 used iris lenses, and 1 used a filter lens. Fifteen percent of patients scored <50 for visual quality; 14 used scleral lenses, 18 used soft lenses, 2 used filter lenses, 2 used iris lenses, 2 used corneal lenses, and 1 used a tinted soft keratoconus lens. Five percent of patients scored <50 in for lens handling; 9 used scleral lenses, and 1 used a tinted soft keratoconus lens. Lastly, 5% of patients scored <50 for overall satisfaction; 5 used scleral lenses, 6 used soft lenses, and 2 used iris lenses.

Table 5. Subjective outcomes measured using a VAS questionnaire with scores ranging from 0-100.

Indication or lens group	No. of eyes, n (%)	Comfort	Visual Quality	Lens Handling	Overall Satisfaction
Total group	281 (100)	84 (14-100)	N/A	N/A	85 (7-100)
Eyes CDVA ≥1/300[a,b]	259 (92)	N/A	76 (4-100)	N/A	N/A
Eyes daily wear	216 (77)	N/A	N/A	86 (15-100)	N/A
Keratoconus	71 (100)	85 (24-97)	N/A	N/A	86 (34-98)
Eyes CDVA ≥1/300[a]	71 (100)	N/A	74 (27-97)	N/A	N/A
Eyes daily wear	71 (100)	N/A	N/A	94 (34-79)	N/A
Dry eye disease	66 (100)	78 (14-100)	N/A	N/A	85 (28-100)
Eyes CDVA ≥1/300[a]	64 (97)	N/A	75 (15-100)	N/A	N/A
Eyes daily wear	29 (44)	N/A	N/A	85 (15-100)	N/A
Keratoplasty:	55 (100)	84 (14-97)	N/A	N/A	85 (15-97)
Eyes CDVA ≥1/300[a]	55 (100)	N/A	84 (14-96)	N/A	N/A
Eyes daily wear	54 (98)	N/A	N/A	85 (44-96)	N/A
Scleral lenses	148 (100)	84 (14-100)	N/A	N/A	85 (15-100)
Eyes CDVA ≥1/300[a]	148 (100)	N/A	77.5 (14-100)	N/A	N/A
Eyes daily wear	148 (100)	N/A	N/A	86 (15-100)	N/A
Soft lenses	99 (100)	84 (14-97)	0	0	85 (26-98)
Eyes CDVA ≥1/300[a,c]	85 (86)	N/A	75 (4-97)	N/A	N/A
Eyes daily wear	34 (34)	N/A	N/A	91 (55-97)	N/A

CDVA = corrected distance visual acuity; VAS = visual analogue scale; VAS outcomes are presented as the median (range); N/A = not applicable.
[a] ≥Distinguish hand motion.
[b] 4 patients didn't complete this question.
[c] 3 patients didn't complete this question.

Effectiveness of the lens selection algorithm

We defined good performance of the lens selection algorithm as an overall satisfaction VAS score >70 (out of 100); this criterion was achieved in 81% of patients. Moreover, 90% of patients reported an overall satisfaction score >60. Importantly, 33% of patients reported an overall satisfaction score >90.

Discussion

The primary goal of this study was to evaluate the objective and subjective performance of various contact lens types that were fitted based on a lens selection algorithm and were used for a broad range of clinical indications. Our results show that similar outcome can be

achieved with both soft lenses and scleral lenses when applying this algorithm. Importantly, subjective comfort, handling, and overall satisfaction were similar between scleral lens users and soft lens users. In addition to underscoring the clinical value of scleral lenses, our results also highlight the need for practitioners to be familiar with a wide range of lens types and tailored lens selection.

A large number of studies have been published recently regarding the indications for—and the application of—medical CLs. In our study, the most common indications were keratoconus, dry eye disease, and keratoplasty; moreover, the most commonly used lens types were scleral lenses and soft lenses (including conventional soft lenses or silicone hydrogel lenses). The objective performance of scleral lenses in our study cohort is consistent with previous reports by our group[15,25,26] and others.[21,22] Specifically, we observed high outcome with respect to median visual acuity**.** The improvement in CL CDVA compared to spectacle CDVA was the most pronounced in the patient subgroups with optical indications (i.e., the keratoconus and keratoplasty subgroups). This finding supports the putative optical benefit of CLs and is consistent with other studies that report on the use of lenses (including scleral lenses) for medical indications with irregular astigmatism.[11,21,22] With respect to therapeutic lenses, CL CDVA improved as well, even though the primary objective of the lenses was to protect or promote healing of the compromised cornea.[6] The optical advantage of lenses (including scleral lenses) in dry eye disease due to compensation of optical disturbances that arise from tear instability, punctate epithelial erosions, and/or corneal scars have been described previously.[28,34,35] Thus, scleral lenses may be preferred when soft lenses fail, and scleral lenses may even surpass soft lenses in terms of hydrating the cornea, protecting the cornea, and/or correcting an irregular corneal surface.[28,29]

Subjective lens performance has also been reported previously. Interestingly, although scleral lenses are often considered to be cumbersome to handle, our study cohort reported remarkably high overall satisfaction, regardless of lens type. Studies of CL performance in which different lens types were evaluated simultaneously in a clinical setting and with various indications have not been reported previously. This paucity of comprehensive studies prevents a comparison of either objective or subjective outcomes, as study design, patient selection, and the types of lenses vary widely. Moreover, the indications for CLs are continuously changing due to developments in ophthalmology.[1] Thus, our study is the first to provide an overarching perspective, and our lens fitting algorithm can support the practitioner in selecting the most appropriate lens type.

Our study has several notable strengths. First, the CL practitioners in this study participate in continuing education, with an emphasis on the specific skills needed to advise patients in

a tertiary academic clinical setting. Thus, our standardized protocols for lens selection, lens fitting, and patient instruction are the result of many years of experience with a wide range of CLs. Furthermore, all of the major steps and decisions in the lens selection algorithm are based on peer-reviewed literature. In addition, it is important to fit CLs individually when applying bandage CLs to complicated eyes,[10,27] which is reflected in our flow chart for soft lenses and silicone hydrogel lenses. Thus, the appropriate material, parameters,[10] modulus,[31] and replacement strategy are all essential for achieving an optimal lens fit. Importantly, our contact lens service is not affiliated with any CL manufacturer, and health insurance companies reimburse patients for CLs prescribed due to medical indications. Therefore, lens selection was not guided by any factors other than the individual patients' needs and preferences. Another strength of this study was our random selection of unilateral eyes; this step was important, given the high degree of correlation between eyes with respect to lens performance. Lastly, subjective performance was analyzed solely in the eye under study, thus further avoiding any possible undue effects due to the performance of the other eye.

This study also had some considerations that merit mention, the most important of which is patient selection. Our contact lens service is in a tertiary academic center, and this may have resulted in a disproportionate selection of more severe clinical indications. Because of its excellent cornea unit, our ophthalmology department has a relatively large population of patients with severe dry eye and—at the other end of the clinical spectrum—a relatively large proportion of post-graft and keratoconus patients. Thus, our clinic is an interregional referral center for patients with keratoconus, and the most severe cases are referred to our contact lens service for evaluation and—if needed—revision of their current CLs. The stage of the disease limited the available lens types to more advanced solutions; thus, a relatively higher proportion of scleral lenses were prescribed, whereas other lens types (for example, RGP corneal lenses) were underreported. Wu et al.[24] illustrated this phenomenon by reporting that RGP corneal lenses do not ensure improved quality of life for patients with severe keratoconus; thus, Wu et al. stressed the importance of prescribing the appropriate CL type for each grade of keratoconus. Moreover, patients may require refitting as their disease stages change,[6] and the optimal CL type for an irregular cornea should not be determined solely by the degree of irregularity. Secondary features such as tear film deficiency and elevated corneal scars can also play an important role, as summarized in our lens selection algorithm.

Interestingly, we found that 58% of patients previously wore different lenses, and the new lens type yielded a high level of overall satisfaction. This result suggests that the majority

of patients wore lenses that were not optimally fitting prior to changing their lens type. Expanding this prospective study to include a more general population will likely reveal important information regarding various CL types in patients in earlier stages of disease.

A limitation of our study was the fact that the cross-sectional observational design did not allow us to study complications associated with the lenses. Thus, we were unable to evaluate the safety, durability, or refractive stability of the lenses. Interestingly, however, four of the 281 patients in our study cohort needed (relatively minor) revision in their lenses (all four of which were scleral lenses); these revisions were based on either suboptimal fitting or altered corneal refraction. This finding is consistent with our previous finding that updating scleral lenses with relatively minor changes every 1.5-2 years is common practice and is recommended in order to ensure the lens material's quality and oxygen permeability.[26] A detailed analysis of these four cases did not provide additional insight (data not shown). In their recent review of scleral lenses, Van der Worp et al.[21] concluded that adverse events are rare in these modalities. In addition, other studies found that the therapeutic use of CLs does not appear to affect the incidence of CL-related complications.[3-6,9] The availability of silicone hydrogel materials with high oxygen permeability has opened new opportunities for patients with hypoxia-related corneal complications. Indeed, several studies reported that silicone hydrogels are both safe and efficacious when worn continuously for therapeutic purposes.[3,7,8] Nevertheless, it is obvious that the wearing of CLs involves some risk, and care should be exercised when fitting a compromised eye. Patients must be educated regarding proper lens care and to identify signs of potential complications before they begin using medical CLs.

The high subjective performance of all CL types was reflected by the fact that patients reported wearing their CLs many hours per day and many days per week; likewise, the VAS scores were relatively high with respect to comfort, visual quality, lens handling, and overall satisfaction. Thus, the lens selection algorithm was found to be effective in terms of subjective overall satisfaction. On the other hand, relatively low subjective performance was reported by a small group of patients, which was expressed by lower VAS scores (i.e., <50) and shorter daily use (<8 hours per day). The lack of longitudinal follow-up in these lower-performing patients precludes our ability to draw any conclusions regarding whether the lower scores are related to CL performance and/or the underlying disease. In general, good wearing time results[21,22,23,35] and good general subjective outcomes have been reported among patients who use scleral lenses,[15,25] although poor outcome has been reported for some patients.[21] Wu et al.[24] reported good vision-related quality of life among patients with a non-severe stage of keratoconus who used appropriate corneal

CLs. Interestingly, the results of the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) studies[36,37] support this finding, although the CLEK study found slightly more ocular discomfort among RGP corneal lens wearers,[36] and patients with keratoconus generally grow increasingly less tolerant to wearing rigid contact lenses.[37] Lastly, Erdurmus et al. [18] reported that patients with keratoconus experience similar CL impact on quality of life, regardless of whether they use RGP corneal lenses, hybrid lenses, or soft toric CLs.

With respect to subjective performance and lens handling, scleral lenses were similar to soft lenses when applying the lens-selection algorithm. This finding is somewhat remarkable, given the initial psychological resistance that patients often express in response to scleral lenses. Nevertheless, other studies have reported similar patient satisfaction results among patients who use scleral lenses.[14,15,29]

In conclusion, we comprehensively evaluated the objective and subjective performance of a broad range of contact lens types used for a variety of clinical indications. Our results revealed that high outcome can be achieved when applying the lens-selection algorithm in terms of visual acuity and overall patient satisfaction. Our results also underscore the role of scleral lenses in modern contact lens practice, and they emphasize the need for the availability of several CL types in order to fit the CL to each patient's needs and preferences. Thus, our lens selection algorithm is effective and can help practitioners select the appropriate CL type.

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Chapter 3

Advantages of toric scleral lenses

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Abstract

Purpose: The purpose of this study was to investigate whether back-surface toric scleral lenses stabilized (i.e., returned to their original position after rotation) and how long the return times were. Return time was studied in relation with actual wearing time and comfort; moreover, the performance of the spherical scleral lens was compared with the toric scleral lens design.

Methods: Toric scleral lenses were rotated clockwise and counterclockwise over 60°. Return times and the actual wearing time were recorded. Results were transformed into nasal and temporal return times for symmetry reasons. The present and former types of correction were compared for comfort (ranging from 0: very poor to 10: excellent) and regular wearing time. All the subjects attended regular follow-up visits.

Results: Forty-three subjects (43 lenses) entered the study. All the lenses returned to the original position within a median of 4 seconds after nasal rotation and 6 seconds after temporal rotation. A significant correlation was found between mean return times and actual wearing time (r = 0.63). Significant increases in median comfort (from 6–8) and median wearing time (from 15–16 hours) were demonstrated when the toric scleral lens designs were compared with the former type of correction (both $P<0.001$). Median comfort and median wearing time also increased significantly after changing from spherical scleral lenses to the toric design (from 7–8 and from 14–16 hours, both $P<0.001$, n=27 eyes).

Conclusions: Toric scleral lenses returned rapidly to their original position after rotation. The flattest meridian of the toric scleral lenses stabilized symmetrically. Patient interviews demonstrated differences in comfort and wearing time in favor of the toric design.

Introduction

Scleral lenses are indicated for several ocular disorders and can often be fitted successfully when corneal and hydrogel contact lenses fail.[1-5] They can be used when the cornea is distorted, to provide mechanical protection, relief of symptoms or facilitate healing. The main indication is optical correction of an irregular corneal surface.[3,6-8] Keratoconus and penetrating keratoplasty are the major group indications, but other forms of irregular astigmatism are also encountered. Mechanical protection and improved function can be achieved in conditions such as entropion, scarred eyelids, and ptosis.[9] Furthermore, the lenses can relieve symptoms, for example in dry eyes, corneal dystrophies, and facilitate healing of recurrent erosions.[10-13] The potential value of overnight wear has been described for recurrent corneal erosions, corneal exposure and some ocular surface diseases, but the hypoxic effect can be a limiting factor.[4,14-16]

The success of scleral lenses lies in the creation of a neutralizing tear lens, corneal clearance and the retention of a precorneal reservoir, whereas the rigidity of the material affords mechanical protection and optical correction.

High oxygen-permeable materials and preformed fitting techniques have considerably extended the use of the scleral lens.[7,9,10,11,17-19] Moreover, technological innovations in the design and manufacturing of these lenses over the past decade have enabled more precise fitting techniques.[9] There have also been two important developments in the precise sub micron lathing fabrication of the scleral lens. First, a front surface cylinder can be lathed onto the scleral lens to correct any residual astigmatism. Second, a back-surface toric scleral part can be lathed for toric scleras to avoid air bubbles being trapped underneath the lens and to prevent local blanching of the conjunctival scleral vessels, which occur in toric or irregular anterior scleral surfaces, causing tissue changes and discomfort.[3,13] These fitting problems were described by Bier and Lowther[20] in 1977, who advised the use of spherical oval fitting or toroidal shells in cases with higher scleral toricity. To resolve these problems, it is essential that toric scleral lenses (in which the haptic back surface is toric) maintain their position. Moreover, constant stabilization enables correction with a front cylinder and other optical corrections such as bifocal, prisms, and aberrations, if indicated. We investigated whether toric scleral lenses stabilized (i.e., returned to their original position after rotation) and how long it took. Return time was studied in relation with actual wearing time and comfort. Furthermore, the performance of the spherical scleral lens was compared with the toric designs.

Materials and methods

All the subjects were wearing one or two well-fitted nonfenestrated toric scleral lenses. After receiving informed consent from the subjects (or their legal representatives in the case of minors) data were collected at the first visit in the 2-month study period. Subjects who made an emergency visit or came for (re-)fitting were not admitted to the study. Lenses were being worn on a daily basis.

The study group had been referred to our contact lens clinic by their ophthalmologist, because they had not responded adequately to other contact lens or therapeutic management.

A previously described preformed fitting methodology was followed to fit the lenses.[1,3,9,10,13] The design was developed in cooperation with Procornea, a rigid lens laboratory (Procornea, Eerbeek, the Netherlands).

The scleral lenses were manufactured at Procornea by precise submicron lathing from Boston Equalens II blanks of 27 mm in diameter and 13-mm thick. They were made of fluorosilicone acrylate copolymer (generic name: itaflurofocon B) manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA. The Dk was listed as 85 X 10^{-11} cm^3 O_2 (cm/ [(sec) (cm^2)(mmHg)]) at 35° centigrade, ISO/Fatt method. The center thickness of a –3.00 D scleral lens was 0.50 mm.

During the fitting procedure, the first diagnostic lens was selected after on-eye assessment of the corneal and scleral shape. Several parameters needed to be empirically determined by evaluation of the diagnostic lens fitting, namely total diameter (range, 18.0-25.0 mm; 0.5-mm steps), scleral radius (range, 11.75-15.0 mm; 0.25-mm steps), central radius (range, 6.60-9.00 mm; 0.30-mm steps) and sagittal depth (range, 3.57-5.37 mm; 0.10-mm steps). In all the scleral lenses, the haptic back surface was toric (toricity of 0.8 mm). Fitting was based on resting of the lens on the external sclera and vaulting of the cornea and limbus. To retain normal corneal physiology, a constant tear flow was required. The ideal lens was characterized by a well-balanced haptic bearing, gentle movement of the lens with pushup test, approximately 0.25 mm of corneal clearance, and 0.05- to 0.10-mm limbal clearance.

Data were recorded during patient interviews, observation, and examination. We recorded age, gender, former type of correction, comfort (ranging from 0: very poor to 10: very good) and wearing time (hours per day) of the former and current types of correction, as well as the duration that the toric scleral lens had been *in situ* at the time of the investigation. Differences were computed between the new and former comfort values and the new and former wearing times. Age was classified in groups of 10 years.

The stabilization axis was established with a slit lamp; a narrow slit was projected parallel to the engravings on the lens (that indicate the flattest meridian) and the axis was read from the protractor. Next, the scleral lens was rotated clockwise over 60°, and the number of seconds it took for the lens to return to its original position was timed with a stopwatch. Then the lens was rotated counterclockwise in the same manner. Subjects were sitting down during this procedure and they were allowed to blink freely. The results of the right and left lens tests were transformed into nasal and temporal return times for analysis.

Because the data did not show a normal distribution (Shapiro-Wilk test, all *P* values of <0.05), the variables were characterised with nonparametric summary statistics: median, range, and quartiles. Spearman rank correlation coefficients were computed. Wilcoxon signed rank test was used to assess the differences in comfort and wearing times within subject and eye groups. Wilcoxon rank sum test was used to test differences between groups. Relative frequency of complete returns was computed with 95% confidence intervals. All the statistical tests were performed in a two-tailed manner and p values of 0.05 or less were considered to be significant. The statistical analysis was applied to one lens per subject. In subjects with two lenses, one lens was selected at random with SAS procedure RANUNI. The other lens was excluded.

Results

A total of 43 subjects (61 lenses) entered the study, 30 right eyes and 31 left eyes. Eighteen subjects were wearing toric scleral lenses in both eyes, 12 subjects were wearing a right lens only and 13 subjects were wearing a left lens only. There were 32 males and 11 females; age ranged from 13 to 78 years, with a median of 39 years. The majority of subjects were between 20 and 50 years of age (34 subjects, 79%) (Table 1). Forty-three lenses were studied after random selection of one lens per subject (23 right eyes and 20 left eyes).

The distribution of the former type of correction is presented in Table 2. Spherical scleral lenses accounted for the former type of correction in 27 eyes (63%), whereas other types of correction or no correction had been worn in 16 eyes (38%).

Table 1. Age distribution of the subjects (n=43 subjects).

Age	No. of subjects, n (%)
13-19 Yrs	1 (2)
20-29 Yrs	9 (21)
30-39 Yrs	13 (30)
40-49 Yrs	12 (28)
50-59 Yrs	3 (7)
60-69 Yrs	4 (9)
70-79 Yrs	1 (2)

Table 2. Type of correction before scleral lens fitting (n=43 subjects).

Former type of correction	No. of subjects, n (%)
No correction	2 (5)
Glasses	2 (5)
Rigid gas-permeable corneal contact lens	7 (16)
Soft contact lens	2 (5)
Piggyback	3 (7)
Spherical scleral lens	27 (63)

The median axis of stabilization of the flattest meridian of the lens was 137° (range, 30-180°) in the right eyes and 47° (range, 170°-0°) in the left eyes. After correction for symmetry, no differences in stabilization axes could be found between the right and left eyes (P= 0.52). After rotation in both directions, all 43 lenses returned to their original position (95% confidence interval: 93-100%). Median return time was 4 seconds (range, 2-60 seconds) after nasal rotation; 50% of the return times (interquartile range) were between 3 and 9 seconds (total range, 2-60 seconds). After temporal rotation, median return time was 6 seconds (range, 1-17 seconds); 50% of the return times were between 4 and 8 seconds. No differences in clockwise, counterclockwise, nasal, temporal, or mean return times could be demonstrated between the right and left eyes (all P>0.82).

A moderate and significant correlation was found between the mean return times and the actual wearing time (r = 0.63). Longer wearing durations at the time of investigation showed longer mean return times. No significant correlation could be demonstrated between age and mean return time (r = 0.11).

Median rating for comfort with the former type of correction was 6 (n=41; range, 1-9); with the present toric scleral lens, this increased to 8 (n=43, range 6-10), which was significant (P<0.001). Median wearing time of the former type of correction was 14 hours a day (n=41; range, 2-16 hours), whereas median wearing time of the present lens was 16 hours a day

(n=43; range, 8-16 hours). This increase was also significant (P<0.001). The two eyes without former correction were excluded from these comparisons.

No correlation could be demonstrated between the present comfort value or present wearing time per day and the return times.

In 27 eyes whose former correction type had been spherical scleral lenses, median comfort increased significantly by one point after changing to the toric design (P<0.001). Median wearing time showed a significant increase of 2 hours in this group of subjects (P<0.001) (Table 3).

Table 3. Median results of former (spherical) scleral lenses and present (toric) scleral lenses (n=27 subjects).

	Former, median (range)	Present, median (range)
Comfort (scale 1-10)	7 (4-9)	8 (6-10)
Wearing time (hours)	14 (2-16)	16 (8-16)

Discussion

Back-surface toric scleral lenses are designed for rotational stabilization. At dispensing and follow-up visits, it is common practice to verify that the lens orientates correctly. One very useful test is to rotate the lens and determine whether it returns to the original orientation. We standardized this test procedure by rotating the lens over 60° and recording the return time in seconds. The 95% confidence interval (93-100%) of this intervention indicated that nearly all the lenses will return to the baseline position.

In this study, all the lenses returned relatively rapidly in the nasal or temporal direction after they had been rotated. Moreover, all 18 of the nonselected lenses also returned to their original position. This apparently reliable stabilization of the toric scleral lens therefore makes it possible to apply a front surface cylinder or other types of optical correction to this lens such as bifocal, prism, and aberration.

The moderate correlation of 0.63 between longer return times and longer actual wearing time could be explained by fit of the scleral lens becoming tighter during the course of the day. Due to gradual (mucus) deposits and a decrease in the wettability of the lens surface during the day, the lens may settle more closely to the eye. Moreover, the bulbar conjunctiva may swell slightly. To confirm this suggestion of tighter scleral fitting, other investigations will have to be performed such as removing each lens and replacing it before every rotation or measuring the return times in the morning and afternoon.

The flattest meridian of the toric scleral lens stabilized symmetrically. A median axis of 137° in the right eye was almost a mirror image of the median axis of 47° in the left eye. Thus, no difference could be demonstrated between the right and left eyes. Anatomic structure of the eyeball, eye muscles, or eyelid tension was probably responsible for this symmetry.

The interview revealed that the subjects were very satisfied with the toric scleral lenses. Median comfort was 8 (scale 1-10) and median wearing time was 16 hours per day. Various studies on gas-permeable scleral lenses used different methods to assess the wearing time, which makes it difficult to compare the results directly. In the study by Kok and Visser,[10] 83% of the 50 eyes were wearing the lenses for more than 8 hours, which was the longest wearing time that could be given in answer to the question. Tan et al.[18] reported wearing times of between 8 to 11 hours in 15 out of 66 eyes and more than 15 hours in 33 eyes. In an ocular surface study, Romero-Rangel et al.[11] observed a mean wearing time of 13.7 hours per day (range, 4-18 hours; n=75 eyes). Segal et al.[21] mentioned a mean wearing time of 16.2 hours (range, 3-18 hours; n=66 eyes). In the latest report by Pullum et al.,[5] 59% (n=538 patients) of the patients were wearing their lenses for an average of 10 hours of more per day. Results can be affected by the diagnoses included in the study groups and may also depend on the definition of wearing time in subjects who wear their lenses all day long.

Several investigators reported prolongation of scleral lens wearing time and improvement in comfort with gas-permeable materials.[1,7,10,11,17,18,22-24]

In the present study, the advantages of the toric scleral lens design were reflected by the increases in wearing time comfort. In 27 eyes that had been wearing a spherical scleral lens before the toric scleral lens, comparisons could be made between the two scleral lens designs. The results showed an increase in median comfort by one point and an increase in median wearing time of 2 hours in favor of the toric scleral lenses. Owing to the more balanced distribution of pressure on the sclera, this lens may be less stressful to the eye and more easily tolerated than the spherical designs. In our study, it was not possible to investigate differences between the two designs at the same lens age in the same patient. Further studies on homogenous groups are necessary to reveal differences between the lens designs, and it would be worthwhile to collect data after longer wearing durations of the toric scleral lenses.

Conclusion

Scleral lenses could be used successfully in the visual rehabilitation and management of subjects with various forms of ocular pathology. The main indication was optical correction of an irregular corneal surface. After rotation, the back-surface toric scleral lens returned to its original position. This reliable stabilization means that front surface cylinders can be used and other optical corrections such as bifocal, prism, and aberration correction. The flattest meridian of the toric scleral lenses stabilized symmetrically. Differences in the comfort and wearing times of the spherical and toric designs were demonstrated in patient interviews in favor of the toric scleral lenses. These results should be considered as indicative.

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Chapter 4

Modern scleral lenses part I: clinical features

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Abstract

Purpose: To evaluate the indications for modern scleral lenses and their clinical performance in patients who were fitted with scleral lenses at the authors' practices.

Methods: In this cross-sectional survey, all the necessary data were obtained at the first follow-up visit during the 5-month study period. There were four types of scleral lenses: spherical, front-surface toric, back-surface toric, and bitoric. The preformed scleral lens fitting technique developed at Visser Contact Lens Practice was used in all patients. The lenses were cut by precise Sub Micron Lathing from a Boston Equalens II blank at Procornea. Visual acuity and slit lamp findings were recorded. A specially designed classification for scleral lens fitting was used to investigate clinical performance.

Results: The largest proportion of the 178 patients (284 eyes) were diagnosed with keratoconus (143 eyes [50.4%]) followed by postpenetrating keratoplasty (56 eyes [19.7%]). The remaining diagnoses were irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses. The ratio of spherical to back-surface toric designs was 1:1.1. Clinical examination showed sharp increases in visual acuity (median increase, 0.45) and safe physiological responses of the anterior eye. All the patients could continue to wear scleral lenses, with 79.2% with the same lens parameters.

Conclusions: Several types of corneal abnormality were managed successfully with modern scleral lenses. The main indication was optical correction of an irregular corneal surface. Satisfactory clinical performance meant that all the patients could continue to wear their scleral lenses.

Introduction

Modern scleral lenses are indicated for several ocular conditions and can nearly always be fitted successfully.[1-5] A scleral lens provides optical correction, mechanical protection, relief of symptoms, and facilitation of healing. It creates a neutralizing tear lens that corrects any corneal irregularities, and it retains a precorneal reservoir. The rigidity of the material affords mechanical protection and optical correction of the corneal surface.

One of the main goals of scleral lens fitting is visual rehabilitation of an irregular corneal surface, such as in primary corneal ectasia (mostly keratoconus), postpenetrating keratoplasty, and other forms of irregular astigmatism.[4-8] Scleral lenses can provide mechanical protection and restore function in conditions such as scarred eyelids, entropion, and ptosis.[9] Furthermore, they can be used to relieve symptoms, as in dry eye and corneal dystrophies and to facilitate healing in the case of recurrent corneal erosion.[10-13]

The potential value of wearing scleral lenses overnight has been described for recurrent corneal erosions, corneal exposure, and various ocular surface diseases. Apparently, the hypoxic effect can be a limiting factor.[3,14-16]

The development of materials with high gas permeability, together with various technological innovations in the design and manufacturing of scleral lenses has opened new perspectives for their use.[7,9,10,17-22] For example, two fairly recent refinements (i.e., a front-surface cylinder and a partial back-surface toric) enabled optimized correction and fitting of the lens. This has resulted in four types of scleral lens: spherical, front-surface toric, back-surface toric, and bitoric.[5;13]

The aims of this prospective study were to evaluate the indications for modern scleral lenses and their clinical performance. Patient satisfaction is presented in section II.

Materials and methods

Data were gathered for this cross-sectional survey between September 1, 2002 and January 31, 2003. Patients were recruited at the scleral lens clinics of Visser Contact Lens Practice in Nijmegen, Utrecht and 's-Hertogenbosch, The Netherlands. Data were collected from all the patients who fulfilled the selection criteria at their first follow-up visit. They were all of legal age, able to complete the questionnaire, and they all gave written informed consent. Any patients who made an emergency visit or came for a refitting were excluded from the study. All the patients had been referred to the clinic by their ophthalmologist because of

one of the indications described earlier, which had not responded to other contact lenses or therapeutic management.

A total of 178 patients (284 eyes) entered the study and included 98 men and 80 women. Age ranged from 18 to 80 years (median, of 41.7 years; mean, 45.0 ± 14.8 years). Most patients (96 patients [53.9%]) were between 30 and 50 years of age. Scleral lenses were being worn in both eyes in 106 patients, in the right eye only in 36 patients, and in the left eye only in 36 patients. There were 142 right eyes (50.0%) and 142 left eyes (50.0%), which resulted in a right to left ratio of 1:1.

All the patients had been wearing one or two scleral lenses for at least 3 months that had been fitted according to the standardized fitting methodology developed by Rients Visser.[1,5,9,10,13] The scleral lens design was realized in cooperation with Procornea (Eerbeek, The Netherlands).

The scleral lenses were manufactured at Procornea by precise Sub Micron Lathing from Boston Equalens II blanks (Polymer Technology, Wilmington, MA) of 27 mm in diameter and 13 mm in thickness. They were made of fluorosilicone acrylate copolymer (itaflurofocon B) manufactured by the Polymer Technology Corporation, Bausch & Lomb. The Dk was listed as 85 X 10^{-11} cm^3 O_2 (cm/[(sec)(cm^2)(mm Hg)]) at 35°C (International Organization for Standardization [ISO]/Fatt method). The center thickness of a –3.00 diopter scleral lens was 0.50 mm.

The scleral lens types applied to our patients included 128 spherical scleral lenses (45.1%), five front-surface toric scleral lenses (1.8%), 71 back-surface toric lenses (25.0%), and 80 bitoric scleral lenses (28.2%). This resulted in a 1:1.1 ratio of back-surface spherical designs (spherical and front-surface toric) to back-surface toric designs (back-surface toric and bitoric).

During the empirical fitting procedure, the cornea and sclera were evaluated to select a trial lens. Then, several parameters were determined for the definitive lens on the basis of the trial lens: power, total diameter (range, 18.0-25.0 mm in 0.5-mm steps), scleral radius (range, 11.75-15.0 mm in 0.25-mm steps), central radius (range, 6.60-9.00 mm in 0.30-mm steps), and sagittal depth (range, 3.57-5.37 mm in 0.10-mm steps) (Figure 1). An optional parameter was a blanching offset (range, 0.1-0.6 mm in 0.1-mm steps). In case of back-surface toric designs, the haptic back surface was toric, with a toricity of 0.8 mm. The fitting was based on resting the lens on the external sclera and vaulting of the cornea and limbus (Figure 2). To retain normal corneal physiology, a constant tear flow was required. The ideal lens was characterized by a well-balanced haptic bearing, gentle movement of the lens with pushup testing, approximately 0.25 mm of corneal clearance, and 0.05 to 0.10 mm limbal clearance.

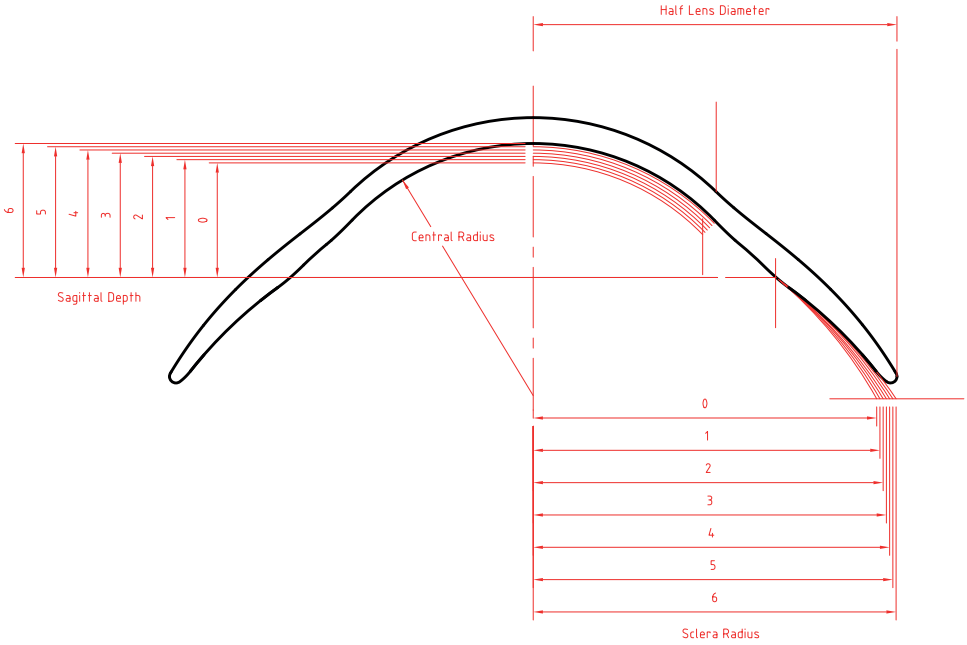

Figure 1. Schematic design of the scleral lens.
(courtesy of B. Wanders, with permission)

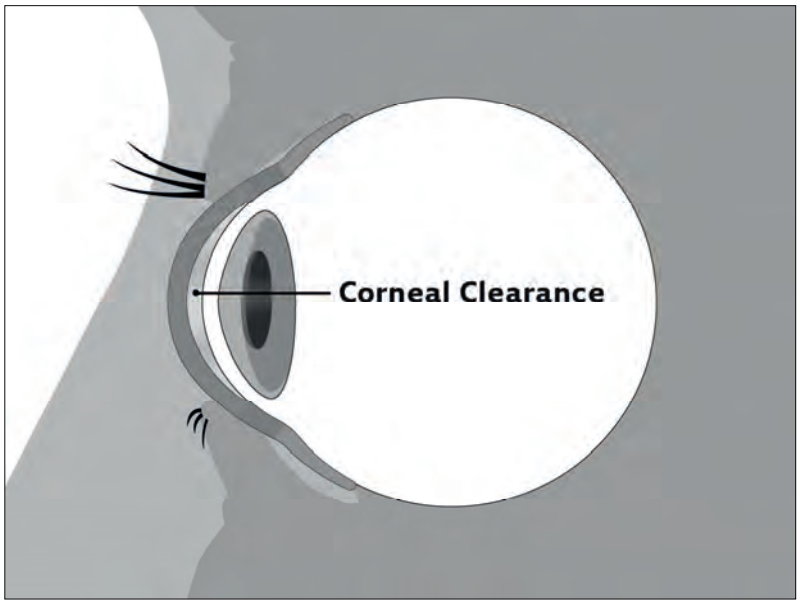

Figure 2. Resting of the scleral lens on the external sclera and vaulting of the cornea and limbus.
(courtesy of B. Wanders, with permission)

The lenses were being worn on a daily basis. Lens care consisted of cleaning, wetting, and disinfecting with standard rigid gas-permeable lens solution systems. Prior to insertion, the lenses were rinsed and filled with unpreserved saline.

Patient data included date of birth, sex, diagnosis, indication for scleral lenses, scleral lens type, front-surface cylinder, dispensing date, starting date of wearing the scleral lens, and starting date of current scleral lens type.

Visual acuity (VA) was measured and noted in decimal form with the scleral lens and with the best-corrected refraction without the scleral lens. The best-corrected refraction was determined by subjective refraction without any contact lens and was performed during the study visit. VA of less than 0.1 was indicated using the following steps: 1/300, 2/300, and 3/300 for hand motions at 1, 2, and 3 m. For finger counting at 1, 2, and 3 m, the VA steps were 1/60, 2/60, and 3/60. To convert Snellen VA to decimal VA, the numerator is divided by the denominator. Thus, the result 20/40 is equivalent to the decimal score of 0.50.

A classification for scleral lens fitting was developed to describe corneal clearance, limbal clearance, scleral fit, lens movement, trapped air bubbles, front surface wettability, front surface deposits, and back surface deposits (Table 1). The 1997 ISO 11980 for Ophthalmic Optics was used as a basis to classify scleral lens fitting and the slit lamp findings.

Slit lamp findings were recorded on the following 10 topics: epithelial edema, stromal edema, corneal infiltrates (epithelial infiltrates and presence of stromal infiltrates at grade 4), corneal vascularization, corneal staining with fluorescein, limbal hyperemia, bulbar conjunctival hyperemia, palpebral signs, anterior blepharitis, and posterior marginal blepharitis. In this study, the ISO standard was extended to include the latter two items. All the topics were classified on a five-point scale, with 0 for none, 1 for trace, 2 for mild, 3 for moderate, and 4 for severe. The investigators used a more detailed explanation to grade each topic. To differentiate scleral lens findings from existing findings before scleral lens wear or findings related to underlying pathology, the investigator was asked to indicate whether or not a sign was related to the scleral lens.

Treatment outcome was recorded as one of the following options: continue, replace current lens, refit with scleral lens, discontinue wearing the scleral lens, and other.

Patient data were recorded on a case report form. The forms were checked for completeness within a few days of the follow-up visit.

Data were stored on a computer with the EPI-INFO package (public domain software). The file was locked after checking all the data and solving any queries. Then the file was transferred to Statistical Analysis System (SAS) to perform inferences.

Table 1. Classification of scleral lens fitting.

Fitting feature	-2	-1	0 (Optimal)	1	2	3	4
Corneal clearance	<0.1 mm	≥0.1 mm to <0.2 mm	0.2 to 0.3 mm	>0.3 mm to ≤0.5mm	>0.5 mm		
Limbal clearance	Absent	<0.1 mm	Approximately 0.1 mm	0.1 mm to ≤0.2 mm	>0.2mm		
Scleral fit (in primary position)	Circumcorneal blanching	Segmented blanching	Optimal	Increased edge clearance, acceptable	Increased edge clearance with air bubble, unacceptable		
Lens movement	Reduced, unacceptable	Reduced, acceptable	Optimal	Excessive, acceptable	Excessive, unacceptable		
Trapped air bubbles			Absent	Slight, <2 mm in diameter	Moderate, >2 mm to <4 mm in diameter	Severe, >4 mm in diameter	
Front surface wettability			Smooth uniformly reflecting surface	Coarse hazy surface, resolved with blinking and exacerbated with staring	Stable dry (nonwetting) area of some magnitude	Nonwettable lens surface	
Front surface deposits			Absent	Very slight, only visible after tear film drying	Slight, visible deposits easily removed	Moderate, deposits adherent and unremovable	Severe, unremovable deposits and comfort affected
Back surface deposits			Absent, clean surface	Very slight, three spots or fewer of moving particles	Slight, as many as 10 spots of moving particles	Moderate, three or fewer nonmoving deposits adherent to lens	Severe, four or more deposits adherent to the lens or corneal indentation

Groups were compared using the chi-square test for independence or Fisher's exact test in the case of categorical variables. Because none of the continuous variables turned out to be normally distributed (Shapiro-Wilk test for normality), these were characterized with distribution-free measures of location and dispersion and were analyzed with the Kruskal–Wallis test. When the result was significant, the Wilcoxon test was used to investigate which groups differed from each other.

Comparisons of continuous variables within subgroups (i.e., differences) were performed with the signed rank test. Only groups with more than five observations were entered for statistical testing. This meant that the spherical, the back-surface toric, and the bitoric lenses formed the main three lens types.

Because a considerable number of the points in figure 3 were equal (i.e., the *x* and *y* variables had the same value in two or more patients or eyes), a small shift was made in the vertical direction to show how many were equal.

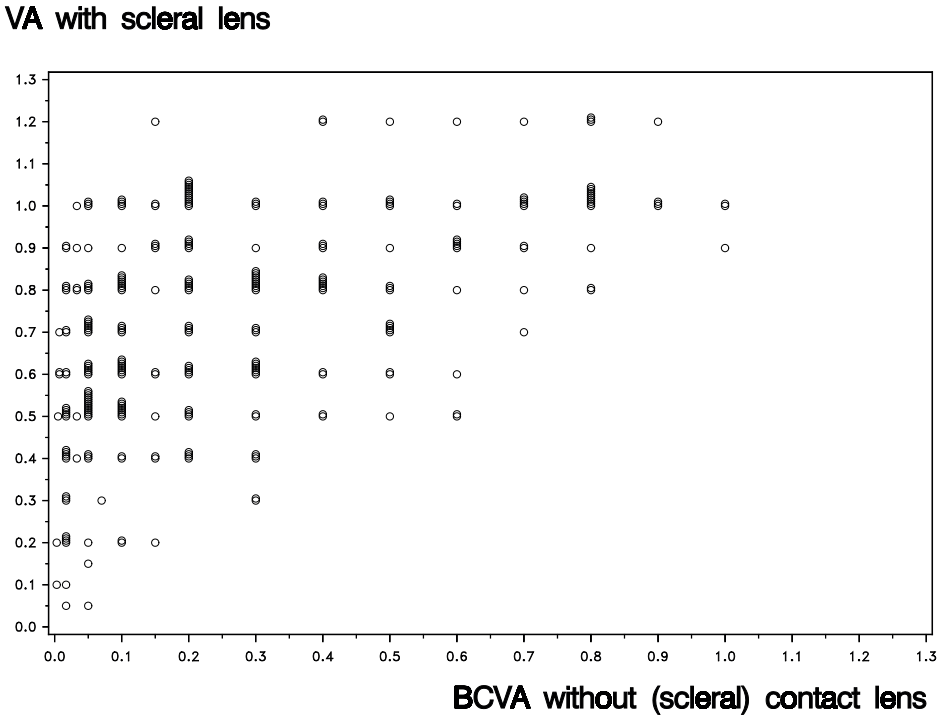

Figure 3. Relation visual acuity (VA) with scleral lens and best-corrected visual acuity (BCVA) without (scleral) contact lens.

All the tests were performed in a two-tailed manner, and *P* values of 0.05 or less were considered to be significant.

The study was approved by the Research and Ethical Committee of the City University, London, United Kingdom.

Results

Underlying scleral lens indication

Diagnoses were categorized into six main groups: keratoconus, postpenetrating keratoplasty, primary or secondary irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses (Table 2). A large proportion of the sample was diagnosed with keratoconus (143 eyes [50.4%]) followed by postpenetrating keratoplasty (56 eyes [19.7%]). Other forms of irregular corneal surface were categorized in the irregular astigmatism group, which included eyes with scars related to herpes simplex keratitis (eight eyes), other forms of keratitis (two eyes), trauma (five eyes), and irradiation (three eyes). The irregular astigmatism group also included six eyes in which the disorder was not further defined, seven eyes with pellucid marginal degeneration, two eyes with pterygium, and one eye with macula corneae. Primary keratitis sicca was seen in four eyes, neurothrophic keratitis in seven eyes, ocular cicatricial pemphigoid in two eyes, and Sjögren syndrome in two eyes. There were four types of corneal dystrophy: map-dot-fingerprint (five eyes), Fuchs endothelial (two eyes), Reis–Bucklers (two eyes), and Lattice (one eye).

Table 2 shows a predominance of men in the first three diagnosis groups. Age varied significantly among the diagnosis groups ($P<0.001$, Kruskal–Wallis test). Patients with keratoconus were younger, and patients who underwent penetrating keratoplasty or had keratitis sicca or corneal dystrophy were older than the other patients (Table 2).

Indications could be categorized into six main groups: visual correction alone, corneal protection, visual correction and ptosis neutralization, corneal protection and visual correction, visual correction and corneal vascularization suppression (after a soft contact lens), and visual correction and tear conservation. Visual correction alone (group 1) was by far the most common indication for scleral lens fitting in this sample and accounted for 249 (87.7%) eyes. The combination of corneal protection and visual correction applied to 19 (6.7%) eyes, and fitting scleral lenses for other reasons applied to 16 (5.6%) eyes.

Table 2. Diagnosis groups, gender, and median age in years.

Diagnosis group	No. of eyes	Men (%)	Women (%)	Minimum	q1	Median	q3	Maximum
Keratoconus	143	84 (58.7)	59 (41.3)	18.2	31.0	37.5	43.1	67.4
Postpenetrating keratoplasty	56	34 (60.7)	22 (39.3)	23.0	43.5	50.5	68.4	80.2
Irregular astigmatism	36	20 (55.6)	16 (44.4)	21.0	35.8	41.3	55.8	79.9
Keratitis sicca	15	3 (20.0)	12 (80.0)	32.5	40.7	52.4	69.6	78.9
Corneal dystrophy	10	5 (50.0)	5 (50.0)	45.6	59.3	66.2	74.6	76.3
Multiple diagnoses	24	9 (37.5)	15 (62.5)	23.3	34.3	45.1	55.5	67.9
All eyes	284	155 (54.6)	129 (45.4)	18.2	33.8	40.7	54.0	80.2

q1, first quartile; q3, third quartile.

Visual acuity

Median VA with scleral lenses was 0.7 and ranged from 0.05 to 1.2. The median best-corrected VA without a (scleral) contact lens was 0.2 (range, 0.003–1). There was a significant increase in VA with a scleral lens compared to the best-corrected VA without a (scleral) lens (P<0.001, signed rank test) (Figure 3). The median increase in VA with a scleral lens was 0.45 and ranged from a decrease of 0.1 to an increase of 1.05.

The highest median increases were seen in eyes with keratoconus (0.50), postpenetrating keratoplasty (0.48), and irregular astigmatism (0.45). Corneal dystrophies showed a median increase of 0.43, followed by multiple diagnoses (0.35) and keratitis sicca (0.20). The level of VA increase differed significantly among the diagnosis groups (P=0.006, Kruskal–Wallis test). Eyes with keratoconus and those that underwent postpenetrating keratoplasty showed greater increases in VA than expected, whereas eyes with irregular astigmatism showed approximately the expected level. In the three remaining diagnosis groups, the increases were lower than expected.

The front-surface toric lens type showed the highest median VA increase (0.60) followed by the bitoric design (0.47) and the back-surface toric type (0.45). The spherical scleral lenses showed a median increase of 0.40. However, these differences were not significant.

In the 106 patients who were wearing scleral lenses in both eyes, the median binocular VA was 0.9 (range, 0.2–1.2). The median best-corrected VA without a (scleral) contact lens was 0.4 (range, 0.017–1.0). The median increase in binocular VA with scleral lenses was 0.4 and varied from a decrease of 0.1 to an increase of 1.05. These differences were significant (P<0.001, signed rank test).

Scleral lens fitting characteristics

The majority of lenses had the optimal value (0) for corneal clearance, limbal clearance, scleral fit, and lens movement. When these values deviated from 0, more of the features had negative values than positive values (Table 3). Almost all the lenses were free from trapped air bubbles. Front surface wettability, front surface deposits, and back surface deposits were optimal or nearly optimal (with slight deviations) in most eyes.

Side effects

In 75 (26.4%) eyes, no positive slit lamp findings were identified. This was indicated as "all negative." In 209 (73.6%) eyes, there were one or more positive slit lamp findings during the examination (Table 4). The lowest percentage of positive findings applied to corneal infiltrates (detected in 2.1% of the eyes) and the highest applied to bulbar conjunctival hyperemia (detected in 48.2% of the eyes).

Table 4 also shows the percentages and frequencies of positive lens-related findings. Corneal infiltrates, anterior blepharitis, and posterior marginal blepharitis were never found to be lens-related. Bulbar conjunctival hyperemia was lens-related in 20.8% of the eyes.

Scleral lens specifications

A front-surface cylinder had been incorporated into 85 front-surface toric and bitoric scleral lenses. The median power of the cylinder was –1.00 and ranged from –0.50 to –2.50.

The median age of the scleral lenses evaluated in the study was 9.8 months (range, 3.1–53.2 months) (Table 5). The back-surface spherical designs were considerably older than the back-surface toric designs.

Significant differences in age were found among the scleral lenses ($P<0.001$, Kruskal–Wallis test). Spherical scleral lenses were significantly older than back-surface toric and bitoric scleral lenses (both $P<0.001$, Wilcoxon tests). There was a slight difference in age between the latter two groups ($P=0.049$) (Table 5).

Table 3. Lens fitting features (n=284 eyes).

Fitting feature	No. of lenses with -2 value (%)	No. of lenses with -1 value (%)	No. of lenses with 0 value (%)	No. of lenses with 1 value (%)	No. of lenses with 2 value (%)	No. of lenses with 3 value (%)	No. of lenses with 4 value (%)
Corneal clearance	14 (4.9%)	58 (20.4%)	163 (57.4%)	48 (16.9%)	1 (0.4%)		
Limbal clearance	7 (2.4%)	67 (23.6%)	173 (60.9%)	37 (13.0%)			
Scleral fit	1 (0.4%)	38 (13.4%)	240 (84.5%)	5 (1.8%)			
Lens movement	6 (2.1%)	59 (20.8%)	206 (72.5%)	13 (4.5%)			
Trapped air bubbles			257 (90.5%)	23 (8.1%)	2 (0.7%)	2 (0.7%)	
Front surface wettability			126 (44.4%)	132 (46.5%)	26 (9.2%)		
Front surface deposits			117 (41.2%)	113 (39.8%)	42 (14.8%)	11 (3.9%)	1 (0.4%)
Back surface deposits			136 (47.9%)	108 (38.0%)	33 (11.6%)	6 (2.1%)	1 (0.4%)

Table 4. Slit lamp findings and relation to the scleral lens.

Slit lamp finding	No. of eyes	No. with grade 0 findings (%)	No. with grade 1-4 findings, lens-related (%)	No. with grade 1-4 findings, non–lens-related (%)
Epithelial edema	284	243 (85.6%)	10 (3.5%)	31 (10.9%)
Stromal edema	284	248 (87.3%)	9 (3.2%)	27 (9.5%)
Corneal infiltrates	284	278 (97.9%)	0 (0.0%)	6 (2.1%)
Corneal vascularization	284	232 (81.7%)	3 (1.1%)	49 (17.2%)
Corneal staining	284	176 (62.0%)	19 (6.7%)	89 (31.3%)
Limbal hyperemia	284	243 (85.6%)	6 (2.1%)	35 (12.3%)
Bulbar conjunctival hyperemia	284	147 (51.8%)	59 (20.8%)	78 (27.5%)
Palpebral signs	284	217 (76.4%)	18 (6.3%)	49 (17.2%)
Anterior blepharitis	284	246 (86.6%)	0 (0.0%)	38 (13.4%)
Posterior marginal blepharitis	284	253 (89.1%)	0 (0.0%)	31 (10.9%)

Table 5. Scleral lens age in months.

Scleral lens type	No. of eyes	Minimum	q1	Median	q3	Maximum
Spherical	128	4.4	13.4	17.7	25.5	53.2
Front-surface toric	5	13.8	13.8	20.8	26.4	26.9
Back-surface toric	71	3.2	4.7	7.8	9.6	23.9
Bitoric	80	3.1	4.7	7.0	8.0	11.6
All types	284	3.1	6.6	9.8	17.6	53.2

q1, first quartile; q3, third quartile.

Patient follow-up

After the interview and examinations, the investigator assessed the performance of the scleral lens (i.e., the outcome of the visit) and made recommendations for the future. For 214 (75.4%) eyes, the plan was to continue to wear the same lens (continuation group). The plan for 11 (3.9%) eyes was to replace the existing lens with a lens with the same parameters (replacement group), and for 59 (20.8%) eyes, the plan was to fit a different scleral lens (i.e., to change the parameters [refit group]). No other options were recommended, such as discontinuing scleral lens wear.

The distribution of the outcomes was significantly different among the lens type groups (P<0.001, χ^2 test) (Table 6).

Nine of the replacements concerned spherical scleral lenses. In the patients with back-surface spherical designs, the age of the existing lens in the continuation group was significantly different from that in the replacement group (P=0.002, Wilcoxon test) (Table 7). This indicated that the scleral lenses that needed to be replaced were older than those in the patients who had been advised to continue wearing their lenses. No other differences could be shown.

Table 6. Outcome for each scleral lens type.

Scleral lens type	No. of eyes	No. of plans for continuation (%)	No. of plans for replacement (%)	No. of plans for refit (%)
Spherical	128	80 (62.5%)	9 (7.0%)	39 (30.5%)
Front-surface toric	5	3 (60.0%)	0 (0.0%)	2 (40.0%)
Back-surface toric	71	62 (87.3%)	2 (2.8%)	7 (9.9%)
Bitoric	80	69 (86.3%)	0 (0.0%)	11 (13.8%)

Table 7. Lens age of back-surface spherical designs.

Outcome	No. of eyes	Minimum	q1	Median	q3	Maximum	*P* Value
Continuation	83	4.4	12.1	16.8	23.5	53.2	0.002
Replacement	9	19.4	21.8	27.9	36.4	48.0	

q1, first quartile; q3, third quartile.

There was no difference in the age of the existing lens or the increase in VA between the continuation group and the refit group. With the back-surface spherical designs, VA with the continuation lenses was significantly higher than that with the refit lenses (P=0.004, Wilcoxon test) (Table 8).

Separate comparisons of lens fitting features were also made on the spherical and toric designs between the continuation and refit groups. With the back-surface spherical designs, significant differences were found in corneal clearance, limbal clearance, lens movement, and front surface deposits. With the back-surface toric designs, significant differences were found in corneal clearance and back surface deposits. Nonoptimal values of the fitting features resulted more frequently to the recommendation to refit the lens.

Table 8. Visual acuity with back-surface spherical designs.

Outcome	No. of eyes	Minimum	q1	Median	q3	Maximum	*P* Value
Continuation	83	0.05	0.60	0.80	0.90	1.00	0.004
Refit	41	0.10	0.40	0.50	0.80	1.00	

q1, first quartile; q3, third quartile.

Discussion

Diagnoses were categorized into six main groups: keratoconus, postpenetrating keratoplasty, primary or secondary irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses. Patients with keratoconus formed the largest group (50.4%), followed by penetrating keratoplasty (19.7%) and other forms of irregular astigmatism (12.7%).

A shift from the application of back-surface spherical designs to back-surface toric designs was expressed in the distribution of these designs 1:1.1. This was not surprising because the experience of the authors is that most bulbi are toric. Unfortunately, no topographical measurements of the bulbus were available to investigate this statement.

Significant increases in monocular and binocular VA were found with a scleral lens compared to the best-corrected VA without a (scleral) lens.

The degree of increase in monocular VA was most marked in the eyes with keratoconus (median increase, 0.50) and those that underwent penetrating keratoplasty (median increase, 0.48).

Most scleral lenses showed optimal lens fitting characteristics, whereas the lens surface characteristics were optimal or nearly optimal in most cases.

To show any side effects of wearing a scleral lens systematically, the slit lamp grading system was used. In 7 of the 10 assessed topics, the frequency of slit lamp signs was less than 20%, and positive findings were nearly always not lens-related. Bulbar conjunctival hyperemia formed an exception, because it was seen more frequently and considered to be lens-related in 20.8% of the eyes.

Nonoptimal values of the lens fitting characteristics and slit lamp grading formed a frequent reason for the recommendation to refit a lens. Refitting a scleral lens was advised in 59 (20.8%) eyes. The experience of the authors is that a proper lens fitting (e.g., a well-balanced haptic bearing, gentle movement of the lens with pushup test, aproximately 0.25 mm of corneal clearance, and 0.05 to 0.10 mm limbal clearance) is essential to avoid complications.

All patients could continue wearing scleral lenses. Three quarters of the eyes continued to wear their existing scleral lens. Replacement without any drastic changes in parameters occurred in 11 (3.9%) eyes. The back-surface spherical lenses that needed to be replaced were significantly older than those that could continue to be worn. This was not surprising, because in general, scleral lenses need to be replaced after 2 or 3 years, depending on deposits and scratches on the lens surface, to guarantee the quality and oxygen permeability of the material. Lens age was a median of 9.8 months and ranged from 3.1 to 53.2 months.

When the underlying corneal topography changed, refitting was usually advised. This was normally the case in progressive anterior eye disorders, such as keratoconus. Many of the back-surface toric and bitoric scleral lenses had been fitted in the past year, which led to relatively new lenses. This was confirmed by the results. Spherical scleral lenses were significantly older than back-surface toric or bitoric scleral lenses.

In the literature, various evaluation methods have led to different results on the performance of scleral lenses. Therefore, it is difficult to make direct comparisons between studies. Since the first successful application of gas-permeable scleral lenses by Ezekiel in 1983, several studies have been published.[17] The current results are compared to the nine most noteworthy and complete studies, when available and applicable. The study designs varied in size, diagnoses, definition of diagnoses, fitting methods, scleral lens types, materials, and so forth. The four largest studies on various diagnosis groups by Tan et al.,[6] Tan et al.,[21] Pullum and Buckley,[7] and Pullum et al.[4] were performed at the Moorfields Eye Hospital, United Kingdom, as was the smaller study by Foss et al.[2] The prospective Dutch study by Kok and Visser,[10] the retrospective Israeli study conducted by Segal et al.,[23] and the retrospective American study by Rosenthal and Croteau[3] also included various diagnosis groups. The study by Romero-Rangel et al.[11] was performed in the United States on one diagnosis group, namely ocular surface disease.

Compared to the other studies, the 178 patients in the current evaluation showed differences in age and sex distributions. There were relatively more women, with a male to female ratio of 1.2:1. Foss et al.[2] reported a ratio of 1.8:1. In the first and second parts of the study by Tan et al.,[6,21] the ratios were 1.6:1 and 1.7:1, respectively. In the two studies by Pullum et al.,[4,7] the ratios were 1.7:1 in both cases. In contrast, Kok and Visser,[10] Romero-Rangel et al.,[11] and Segal et al.[23] reported more female patients, with ratios of 1:1.3, 1:1.7, and 1:1.1, respectively.

The diagnoses included in the aforementioned studies were reflected in the ratios. There were more female patients when a large proportion of the eyes were diagnosed with a form of ocular surface disease, whereas there were more male patients with keratoconus or other forms of primary corneal ectasia and penetrating keratoplasty. Furthermore, Tan et al.[6,21] and Pullum et al.[4,7] reported the highest male-to-female ratios in patients with irregular astigmatism, keratoconus, and penetrating keratoplasty; the ratio was lower in their ocular surface disease group. Table 2 shows the sex distribution per diagnosis group in the present study. The results were similar to those described in the earlier studies. Male predominance was seen in keratoconus, penetrating keratoplasty, and irregular astigmatism; female predominance was seen in keratitis sicca and corneal dystrophy.

Median age in this study was 41.7 years (mean, 45.0 years). The inclusion criteria admitted only patients between 18 and 80 years of age. In the previous studies, all ages were included. Mean age was used for comparison purposes, as most of the papers only mentioned this measure of central location. Our mean age of 45 years in the current study was slightly higher than that in four other studies with various diagnosis groups: 42.9 years in Kok and Visser,[10] 40.8 and 37.7 years in Tan et al.,[6,21] and 39.6 years in Segal et al. [23] Pullum et al.[4] showed a peak at approximately 35 years. Romero-Rangel et al.[11] found a mean age of 44.6 in their patients with ocular surface disease. This was expressed in the current series by the significant variation in age between the diagnosis groups; patients with keratoconus were younger, whereas patients with penetrating keratoplasty, keratitis sicca, or corneal dystrophy were older than the other patients. An explanation for these results is that keratoconus occurs at an earlier age than the several forms of keratitis sicca and corneal dystrophy. Moreover, penetrating keratoplasty can be expected in older patients, because in many cases, the surgery was performed on patients with severe progression of keratoconus. This occurs during the course of the disease and thus at an older age.

Except for Foss et al.,[2] all the studies that included various diagnoses showed, in accordance to the current study, a predominance of deviant corneal topography.[3,4,6,7,10,21,23] Not surprisingly, the main indication for scleral lens fitting in these studies was to improve VA. Percentages reported by Tan et al.,[6] by Tan et al.,[21] and in the current study were 85.8%, 80.3%, and 87.7%, respectively.[6,21] No details will be given on other subgroups, because they were too small.

Contrary to the current study, the British studies also contained aphakia and high myopia as diagnosis groups. The primary corneal ectasia percentage increased, whereas the percentage of aphakes and high myopes declined over the years.[4,7] It was striking that in comparison with the results of the current study, there were relatively more eyes with ocular surface disease in the reports by Kok and Visser[10] (keratitis sicca 31.9%), Foss et al.[2] (ocular surface disorders 45.5%), and Rosenthal and Croteau[3] (374 eyes with severe ocular surface disease of a total of 875 eyes).

The VA results of our study were in line with other reports. Several studies showed sharp improvements in VA with scleral lenses. Our study confirmed the best VA results in the group with deviant topography, in correspondence with other studies.[3,4,6,7,10,21,23] Studies that included indications other than visual correction showed less pronounced improvement in VA in these groups. This was not surprising because this group primarily had a therapeutic indication for scleral lens fitting, namely corneal protection, tear conservation, or pain relief.

The greatest increases in VA were seen in the front-surface toric (median, 0.60) lens designs. The median increase was 0.47 for bitoric, 0.45 for back-surface toric, and 0.40 for spherical scleral lens.

Other investigators studied their patients over a longer period than the current study did. This enabled them to study failure rates during a longer period. In a retrospective study, Tan et al.[6] found that 71% of the eyes could continue to wear the scleral lens, but the remainder reverted to alternative lens types or progressed to surgery. In another study on oxygen-permeable scleral lenses,[21] the authors found that eventually scleral lenses were unsuccessful in 8.0% of the eyes. Pullum and Buckley[7] described that 22% of their cases failed a scleral trial or stopped wearing their scleral lenses completely.[7] A failure rate of 10.4% was reported by Segal et al.[23] In the most recent report by Pullum et al.,[4] the outcome in a total cohort of 1,003 patients (1560 eyes) was that 808 eyes could continue to wear the scleral lens, 56 eyes failed a trial, 42 eyes suspended wearing the lenses temporarily, 145 eyes stopped wearing the lenses, and 508 eyes had lenses in progress or a pending first follow-up visit.

One of the selection criteria in the current study was a minimum scleral lens age of 3 months and patients who came for an emergency visit were excluded from the study. This might have affected the results, in comparison with the other studies that did not use an exclusion criterion of a minimum lens age.

In conclusion, modern scleral lenses could be used successfully for visual rehabilitation and management of a wide range of corneal disorders that have not responded adequately to other treatment modalities. The main indication was optical correction of an irregular corneal surface, especially those surfaces resulting from keratoconus and penetrating keratoplasty. Furthermore, the scleral lens was of benefit in several forms of ocular surface disease. Clinical examination showed sharp increases in VA and safe physiologic responses of the anterior eye. The satisfactory clinical performance of modern scleral lenses meant that their continued application can be recommended in all cases.

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Chapter 5

Modern scleral lenses part II: patient satisfaction

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Abstract

Purpose: To evaluate the subjective performance of modern scleral lenses in patients of the clinics of Visser Contact Lens Practice.

Methods: In this cross-sectional survey, all the necessary data were collected at the first follow-up visit during the 5-month study period. In accordance with the preformed fitting technique developed at Visser Contact Lens Practice, four types of scleral lenses were used: spherical, front-surface toric, back-surface toric, and bitoric. Subjective performance was investigated during an interview that included the use of a five-point Likert scale and by means of a questionnaire supplemented by a 100-mm visual analog scale (VAS).

Results: The interview and questionnaire showed high scores for patient satisfaction with the current scleral lens in our 178 patients (284 eyes) (median score, 4; range Likert scale, 1-5; median score, ≥75; range VAS, 1-100). Significant increases in scores were seen with the current scleral lens compared to the former correction: 78.9% for comfort, 78.2% for visual quality, and 87.7% for overall satisfaction (n=284 eyes) (P<0.001). In the 99 eyes that switched from back-surface spherical to back-surface toric designs, the following significant increases were seen: 61.6%, 37.4%, and 65.7%, respectively (P<0.001).

Conclusions: High patient satisfaction was seen with all the modern scleral lens designs in the management of several forms of corneal abnormality. The interview showed differences in comfort, visual quality, and overall satisfaction in favor of the back-surface toric designs compared to the back-surface spherical designs.

Introduction

Scleral lenses are effective in the management of corneal diseases because they have unique advantages: the retention of a precorneal fluid reservoir that affords simultaneous optical correction of the irregular corneal surface and corneal hydration. The rigidity of the material provides optical correction and mechanical protection.[1,2]

The clinical application of contact lenses began with the work of Fick and Muller in the 1880s.[3,4] These early contact lenses were all haptic or scleral and were made from glass. Several developments followed and included a preformed trial fitting set or molded glass scleral lenses and the introduction of polymethyl methacrylate (PMMA). Later, the application of scleral lenses stagnated because of the introduction of corneal and hydrogel lenses. The latter lenses were much easier to fit, and there were fewer contact lens–related complications, such as those from the hypoxia induced by the previous scleral lenses. However, in view of the therapeutic value of sclerals, Ezekiel[5] evaluated the use of these lenses made from a gas-permeable material in 1983. He reported greater acceptability and comfort of the oxygen-permeable scleral lenses than the PMMA versions. The development of highly gas-permeable materials, well-defined fitting techniques and technological innovations in the design and manufacturing of scleral lenses led to better performance.[2,5-12]

Approximately by 1990, several milestones were reached in the development of scleral lenses. It became possible to apply a front-surface cylinder to improve vision. Second, a back-surface toric scleral part was lathed to avoid air bubbles being trapped underneath the lens and to prevent local blanching of the conjunctival scleral vessels that occurred with toric or irregular anterior scleral surfaces, causing tissue changes and discomfort.[13,14] Such fitting problems were described by Bier[15] in 1977, who advised the use of spherical oval lenses or toroidal shells in cases with higher scleral toricity. These problems can be resolved by maintaining a certain position of the back-surface toric scleral lenses on the eye. In addition, constant stabilization enables correction with a front-surface cylinder and other optical corrections, such as bifocal, prisms, and aberrations, if indicated.

These recent developments have led to four types of scleral lens and have enabled optimized fitting: spherical, front-surface toric, back-surface toric and bitoric.

A prospective study was performed on the subjective performance of scleral lenses to determine the effectiveness of modern scleral lenses.

Materials and methods

Patients were recruited from the three scleral lens clinics of Visser Contact Lens Practice in Nijmegen, Utrecht and 's-Hertogenbosch, The Netherlands between September 1, 2002 and January 31, 2003. Inclusion criteria were that the patient was of legal age, had been wearing one or two scleral lenses made by Procornea (Eerbeek, The Netherlands) for at least 3 months, and had been fitted at one of the authors' practices. Exclusion criteria were the inability to give written informed consent, inability to comply with the study, and making an emergency visit or refitting. All the patients had been referred to the clinic by their ophthalmologist, because they had been diagnosed with one of the indications described in part I of the study: keratoconus (143 eyes, 50.4%), penetrating keratoplasty (PKP) (56 eyes, 19.7%), primary or secondary irregular astigmatism (36 eyes, 12.7%), keratitis sicca (15 eyes, 5.3%), corneal dystrophy (10 eyes, 3.5%), and multiple diagnoses (24 eyes, 8.5%).

The preformed fitting technique, designs, production methods, and lens care were described in part I of the study. Four different types of scleral lens design were being worn by the patients: 128 (45.1%) spherical scleral lenses, five (1.8%) front-surface toric scleral lenses, 71 (25.0%) back-surface toric scleral lenses, and 80 (28.2%) bitoric scleral lenses. This resulted in a 1:1.1 ratio of back-surface spherical designs (spherical and front-surface toric) to back-surface toric designs (back-surface toric and bitoric). Because of the size of the groups, spherical, back-surface toric, and bitoric scleral lenses were considered the three main types.

Demographic and anthropometric data were recorded, as were the details of diagnosis, previous (scleral) lens history, scleral lens type, and parameters. During the interview, the patients were asked to state how many hours a day they had been wearing the lens(es), how many times a day they needed a break from wearing the scleral lens(es), the number of attempts they made before the scleral lens was inserted correctly, and the previous main type of correction before they received the scleral lens(es).

The patients were also asked to rate their level of satisfaction verbally and on a written questionnaire. Scores were obtained for the current lens and the main type of correction before they started wearing the scleral lens(es). Patients wearing back-surface toric designs also rated their former scleral lens. Three topics were covered, namely comfort, visual quality, and overall satisfaction. The Likert scale with verbal descriptors ranged from 1 (very poor) to 5 (excellent).

After the examination, the patients were asked to complete a questionnaire on seven specific dimensions: comfort, lens dryness, visual quality, air bubbles while wearing the lens, debris behind the lens, lens cleanliness, and lens handling. They also gave a score for overall satisfaction. A visual analog scale (VAS) was used to obtain separate scores for the right and the left lenses, from 0 (unacceptable performance) to 100 (excellent performance) mm. The patient was required to sign the bottom of the form.

Scores on the VAS were measured to the nearest millimeter by hand using a ruler. The intersection with the VAS axis was used as the reference point, also in the case of oblique lines. A few of the patients had indicated their scores with a cross instead of a vertical line. In these cases, the middle of the cross was measured.

In addition to the statistical methods described in part I, the relationship between two continuous variables was assessed with the Spearman rank correlation coefficient.

Approval for the study was granted by the Research and Ethical Committee of the City University, London, United Kingdom.

Results

In this study, 178 patients (284 eyes) were recruited. Demographic and anthropometric details and the distribution of diagnoses and scleral lens types were described in part I of the study.

Distributions of the former main types of correction are shown in Table 1. Eighty-seven (30.6%) eyes had not been corrected with contact lenses before the scleral lens. Rigid gas-permeable (RGP) corneal contact lenses formed the former type of correction in 142 (50%) eyes versus the remaining types of contact lens 55 (19.4%) eyes. The group “other” comprised three eyes that had formerly been corrected with SoftPerm and one eye with RGP corneal lenses and glasses.

Table 1. Correction before scleral lens fitting.

Type of correction	No. of eyes, n (%)
No correction	32 (11.3)
Glasses	55 (19.4)
Soft contact lens	24 (8.4)
Rigid gas-permeable corneal contact lens	142 (50.0)
Piggyback	19 (6.7)
Semiscleral lens	8 (2.8)
Other	4 (1.4)

The median total duration of using scleral lenses was 33.9 months (range, 3.3–162.8 months); the median duration of using the current scleral lens type was 10.7 months (range, 3.1–160.0 months). There were significant differences in the total duration of using the scleral lenses among the three main lens groups (P=0.005, Kruskal-Wallis test). Spherical scleral lenses had a longer duration than did back-surface toric designs (P=0.002, Wilcoxon test).

The duration of using the current scleral lens type also varied significantly among the three main lens types (P<0.001, Kruskal-Wallis test). Spherical scleral lenses had been used continuously for longer than the back-surface toric designs (P<0.001, Wilcoxon test).

No differences were found in the total duration of using the scleral lenses or the duration of using the current lens type between the back-surface toric and bitoric scleral lenses.

All the lenses were being worn for a median of 16 hours per day (range, 3–19 hours). Small but nonsignificant differences were seen in the wearing time per day among the diagnosis groups and among the lens groups. Eyes in the keratitis sicca group showed a somewhat shorter median wearing time (14 hours) than the other eyes (15.5 or 16 hours).

Spherical scleral lenses were generally being worn for 1 hour longer per day (16 hours) than the other three scleral lens types (15 hours). The differences between the main three lens types did not reach significance (P=0.052, Kruskal-Wallis test).

The scleral lenses were being worn continuously during the day by 51.1% of the eyes, whereas 48.9% of the eyes needed one or more breaks.

Significant differences were found in the number of breaks between the six diagnosis groups (P=0.005, Kruskal-Wallis test). The relative frequency of one or more breaks was significantly higher (P=0.017, χ^2 test) in the eyes with keratitis sicca or multiple diagnoses (66.7% and 79.2%) than in all the other eyes in this sample (range, 30%–47.6%). The necessity to take one or more breaks during the day was higher with spherical scleral lenses (55.5%) than with the other three types (20.0%, 42.3%, and 46.2%, respectively).

The median number of attempts before the scleral lens was inserted correctly was 1 (range, 1–5). In 64.4% of the eyes, the lenses were inserted correctly on the first attempt, whereas in 35.6% of the lenses, more attempts were needed to achieve correct insertion. No significant differences could be detected in the number of attempts among the six diagnosis groups or the three main lens types.

The scores given by the patients during the interview are shown in Table 2. Scores of 3 or more were given with the former correction by 54.6% for comfort, by 51.8% for visual quality, and by 50.4% for overall satisfaction. Scores of 3 or more were given with the current scleral lens by 98.9% for comfort, by 97.9% for visual quality, and by 98.9% for overall satisfaction.

Table 2. Scores given by the patients in the interview for former correction, former scleral lens, and current scleral lens type.

Interview dimension per correction type	No. of eyes	Minimum	q1	Median	q3	Maximum	Mean	No. of grades 1 and 2 (%)	No. of grades 3, 4, and 5 (%)
Former main type of correction									
Comfort	284	1.0	2.0	3.0	4.0	5.0	2.7	129 (45.4%)	155 (54.6%)
Visual quality	284	1.0	2.0	3.0	4.0	5.0	2.7	137 (48.2%)	147 (51.8%)
Overall satisfaction	284	1.0	2.0	3.0	3.0	5.0	2.6	141 (49.6%)	143 (50.4%)
Former scleral lens									
Comfort	99	2.0	3.0	4.0	4.0	5.0	3.5	10 (10.1%)	89 (89.9%)
Visual quality	99	2.0	3.0	4.0	4.0	5.0	3.8	1 (1.0%)	98 (99.0%)
Overall satisfaction	99	2.0	3.0	4.0	4.0	5.0	3.6	5 (5.1%)	94 (94.9%)
Current scleral lens									
Comfort	284	2.0	4.0	4.0	5.0	5.0	4.2	3 (1.1%)	281 (98.9%)
Visual quality	284	2.0	4.0	4.0	5.0	5.0	4.1	6 (2.1%)	278 (97.9%)
Overall satisfaction	284	2.0	4.0	4.0	5.0	5.0	4.3	3 (1.1%)	281 (98.9%)

Grade 1, very poor; grade 2, poor; grade 3, average; grade 4, good; grade 5, excellent.
q1, first quartile; q3, third quartile.

In the 99 eyes with back-surface toric designs, scores were obtained for the former scleral lens type when it had been a spherical back-surface design. The former types of scleral lens received a score of 3 or more from 89.9%, 99.0%, and 94.9% of the patients for comfort, visual quality, and overall satisfaction, respectively.

In Table 3, comparisons are made of the scores for the current scleral lens, the former main type of correction and, if applicable, the former scleral lens. Significant increases were found in the scores with the current lens for all three topics (P<0.001, signed rank test). Higher scores with the scleral lens were seen in 78.9% of the eyes for comfort, in 78.2% for visual quality, and in 87.7% for overall satisfaction. The increases in scores from the former scleral lens design to the current back-surface toric design were also significant (all P<0.00, signed rank test). The percentages of cases who gave increased scores with the current scleral lens were 61.6% for comfort, 37.4% for visual quality, and 65.7% for overall satisfaction.

Table 3. Increases in scores given by the patients in the interview for the current scleral lens compared to the former correction and former scleral lens.

Interview dimension per correction type	No. of eyes	Minimum	q1	Median	q3	Maximum	No. of eyes with increase (%)
Increase compared to former correction							
Comfort	284	-2,0	1.0	1.0	2.0	4.0	224 (78.9%)
Visual quality	284	-2,0	1.0	1.0	2.0	4.0	222 (78.2%)
Overall satisfaction	284	-1,0	1.0	2.0	2.0	4.0	249 (87.7%)
Increase compared to former scleral lens							
Comfort	99	0.0	0.0	1.0	1.0	3.0	61 (61.6%)
Visual quality	99	-3.0	0.0	0.0	1.0	2.0	37 (37.4%)
Overall satisfaction	99	-2.0	0.0	1.0	1.0	3.0	65 (65.7%)

q1, first quartile; q3, third quartile.

Table 4 shows the scores given in the questionnaire (scale, 0-100). The median score was 75 for lens dryness, debris behind the lens, and lens cleanliness. Comfort and overall satisfaction had a median score of 84. The median score was 80 for visual quality, 85.5 for air bubbles behind the lens, and 87.5 for lens handling.

Table 4. Scores given by the patients in the questionnaire.

Questionnaire dimension	No. of eyes	Minimum	q1	Median	q3	Maximum
Comfort	284	24.0	73.5	84.0	93.0	100
Lens dryness	284	14.0	63.0	75.0	85.0	100
Visual quality	284	17.0	66.0	80.0	90.0	100
Trapped air bubbles	284	27.0	77.0	85.5	95.0	100
Debris behind lens	284	14.0	63.0	75.0	90.0	100
Lens cleanliness	284	24.0	64.0	75.0	85.0	100
Lens handling	284	27.0	80.0	87.5	95.0	100
Overall satisfaction	284	13.0	75.0	84.0	94.0	100

q1, first quartile; q3, third quartile.

In Tables 5 and 6, the three items from the questionnaire, namely comfort, visual quality, and overall satisfaction, are scored per diagnosis group and scleral lens type. The median scores for comfort and overall satisfaction were higher than 80 in all the diagnosis groups, except for keratitis sicca, in which the median score was 74 for comfort and 77 for overall satisfaction. For visual quality, the median scores were 80 or higher in all the groups, except for keratoconus, in which the median score was 75.

The median score for comfort was 74 with the front-surface toric scleral lenses and 80 or more with the other three scleral lens types. The median score for visual quality varied from 64 with the front-surface toric lenses to 84 with the spherical scleral lenses. Overall satisfaction received a median score of 80 or more with the four lens types. No statistical differences could be detected in the three topics between the diagnosis groups or the three main lens types.

With the current scleral lens, Spearman correlation coefficients were all significant between the scores obtained for comfort, visual quality, and overall satisfaction in the interview and in the questionnaire: 0.59, 0.55, and 0.60, respectively (all $P<0.001$).

Table 5. Scores given in the questionnaire per diagnosis.

Questionnaire dimension per diagnosis	No. of eyes	Minimum	q1	Median	q3	Maximum
Keratoconus						
Comfort	143	24.0	73.0	82.0	93.0	100
Visual quality	143	24.0	64.0	75.0	87.0	96.0
Overall satisfaction	143	30.0	74.0	84.0	94.0	96.0
Penetrating keratoplasty						
Comfort	56	24.0	80.0	86.0	94.0	100
Visual quality	56	36.0	75.0	85.0	94.0	100
Overall satisfaction	56	46.0	80.0	90.0	95.0	100
Irregular astigmatism						
Comfort	36	25.0	66.5	80.0	86.5	100
Visual quality	36	17.0	55.5	80.0	85.0	96.0
Overall satisfaction	36	13	74.5	80.0	85.5	100
Keratitis sicca						
Comfort	15	55.0	67.0	74.0	94.0	99.0
Visual quality	15	45.0	54.0	84.0	85.0	98.0
Overall satisfaction	15	54.0	74.0	77.0	85.0	98.0
Corneal dystrophy						
Comfort	10	83.0	84.0	84.0	94.0	94.0
Visual quality	10	36.0	84.0	87.0	94.0	95.0
Overall satisfaction	10	64.0	76.0	93.5	94.0	95.0
Multiple diagnoses						
Comfort	24	24.0	65.0	81.5	91.5	100
Visual quality	24	30.0	80.0	87.0	93.0	96.0
Overall satisfaction	24	26.0	74.5	80.0	91.0	94.0

q1, first quartile; q3, third quartile.

Table 6. Scores given in the questionnaire per scleral lens type.

Questionnaire dimension per scleral lens type	No of eyes	Minimum	q1	Median	q3	Maximum
Spherical						
Comfort	128	24.0	73.5	84.0	94.0	100
Visual quality	128	24.0	70.0	84.0	90.0	100
Overall satisfaction	128	26.0	75.0	84.0	94.0	100
Front-surface toric						
Comfort	5	35.0	50.0	74.0	74.0	93.0
Visual quality	5	40.0	64.0	64.0	73.0	75.0
Overall satisfaction	5	73.0	80.0	85.0	85.0	94.0
Back-surface toric						
Comfort	71	24.0	74.0	85.0	94.0	100
Visual quality	71	17.0	65.0	80.0	93.0	96.0
Overall satisfaction	71	13	75.0	85.0	94.0	100
Bitoric						
Comfort	80	25.0	72.0	80.0	89.0	100
Visual quality	80	34.0	65.0	75.0	90.0	100
Overall satisfaction	80	34.0	74.0	80.0	90.0	95.0

q1, first quartile; q3, third quartile.

Discussion

It has been well-established that scleral lenses can improve visual acuity in irregular corneal astigmatism and decrease the symptoms associated with ocular surface disorders.[1,6,7,12,16-21] The patient satisfaction results support these statements.

Scleral lenses had been fitted in patients because other treatment modalities, including contact lenses, had failed. Almost one third of the eyes had not been wearing any contact lens correction, whereas 50% of the eyes had been fitted with RGP corneal contact lenses before they received a scleral lens. The remaining types of contact lens were soft contact lenses, piggyback systems, semi-scleral lenses, and SoftPerm lenses.

A ratio of 1:1.1 was found between back-surface spherical designs (spherical [128 eyes] and front-surface toric [5 eyes]) and back-surface toric designs (back-surface toric [71 eyes] and bitoric [80 eyes]). Since the introduction of these back-surface toric designs at the authors' scleral lens practices, a shift has occurred from refitting spherical scleral lenses towards these new designs. This is reflected in the scleral lens history of the patients in this series.

The lens age and the total duration of lens use was longer with the spherical scleral lenses than with the back-surface toric designs. Median total duration was 33.9 months (range, 3.3–162.8 months). Durations were longer in the studies by Tan et al. (mean, 11.8 years; range, 3 months–56 years) and Foss et al. (range, 1-40 years).[16,17] In these studies, PMMA materials had mainly been used, which may explain these discrepancies, because PMMA has been available for longer than the modern gas-permeable materials.

All the lens types were being worn for a median of 16 hours per day (range, 3–19 hours; mean, 14.3 hours). Various studies on scleral lenses used different methods to assess the wearing time. Prolongation of lens wearing time has been reported with gas-permeable materials.[1,5-8,11,18,22,23] Foss et al.[16] reported shorter wearing times in their study on PMMA scleral lenses, whereas Tan et al.[11] reported increased wearing times in 85% of the eyes that switched from PMMA to gas-permeable materials. The tendency toward a shorter wearing time in the patients with keratitis sicca in the current study (median, 14 hours per day) supported the study on 76 eyes diagnosed with ocular surface disease by Romero-Rangel et al.[18] In their review, the mean wearing time was 13.7 hours per day (range, 4–18 hours). In contrast, Foss et al.[16] found median values of 8.5 hours in their visual group and 11 hours in their therapeutic group in their PMMA study. The mean wearing time by all the eyes in the current study was lower than the 16.2 hours (range, 3-18 hours) reported by Segal et al.[19] In the study by Kok and Visser,[6] 83% of the 50 eyes were wearing the lenses for more than 8 hours, which was the longest duration that could be indicated on the questionnaire. Tan et al.[17] reported wearing times between 8 and 11 hours in 15 of 66 eyes and more than 15 hours in 33 eyes. In the latest report by Pullum et al.,[21] 59% (n=538) of patients were wearing the lenses for an average of 10 hours or more. Results can be affected by the diagnoses included in the study groups and may also depend on the definition of wearing time in patients who wear their lenses all day long.

The performance of a scleral lens is also reflected in the necessity to take a break from wearing the lens during the day. The interview did not ask about the length of the breaks, because a break normally entails lens removal and cleaning, directly followed by reinsertion. Most (51.1%) patients were wearing their lenses continuously. Tan et al. found that fewer patients with gas-permeable lenses needed to take a break than patients with PMMA scleral lenses. In their first study, 61.7 % of the eyes needed a break, compared to 45.5% in their gas-permeable study.[11,17] Other investigators also mentioned alleviation of discomfort by taking breaks during the day, but they did not investigate exact numbers.[6,16,18,19]

The current study showed that the relative frequency of one or more breaks was significantly higher in the eyes with keratitis sicca (66.7%) and multiple diagnoses (79.2%) than in all

the other eyes in the sample (range, 30%–47.6%). This is in accordance with the advice given to the dry-eye patients by Kok and Visser (i.e., to take the lens out during the day, to refill the lens with saline or a lubricant).[6] Patients with dry eyes tend to experience more debris and deposits, which may be alleviated by cleaning the lens more frequently. In the questionnaire, these patients gave somewhat lower scores for comfort and overall satisfaction than the patients in the other diagnosis groups.

When asked how many attempts were needed to achieve correct lens insertion, 64.4% of the patients reported that they were successful the first time. The most frequently reported difficulty during lens insertion was a trapped air bubble behind the lens.

High scores were given for patient satisfaction with the current scleral lens in the interview and in the questionnaire. These scores correlated significantly between the two rating methods of the three main topics, comfort, visual quality, and overall satisfaction.

A lower median score had been given for comfort and overall satisfaction by the patients with keratitis sicca than by the remaining diagnosis groups. The median score for visual quality was 80 or more in all the groups, except for the keratoconus group, in which the median was 75.

Other studies that reported on the subjective performance of scleral lenses used different methods of assessment. In the first report on gas-permeable scleral lenses, Ezekiel[5] stated that these lenses were more comfortable than lenses made from non gas-permeable materials. The results of the study by Pullum and Buckley confirmed this finding; 36% of the patients reported improvements in comfort with gas-permeable materials, whereas an additional 30% reported increases in the wearing time per day compared to PMMA. There were also improvements in vision in 11% of the cases.[7] Romero-Rangel et al.[18] concluded on the basis of their questionnaire analysis that scleral lenses led to marked relief of ocular discomfort in 40 (82%) patients. Improvements in visual function and quality of life were reported by 45 (92%) patients. These authors also evaluated photophobia and found reduced levels in 37 (75%) patients with scleral lenses. Segal et al[19] published similar results: 35 (81.4%) patients reported marked relief of discomfort and 37 (86%) patients experienced marked improvement in daily activities.

In this series, the current scleral lens received a significantly higher score than the former correction before the scleral lens had been fitted (including no correction). Higher scores were seen for comfort, visual quality, and overall satisfaction in over 75% of the eyes.

In the 99 eyes that had switched from back-surface spherical designs to back-surface toric scleral lenses, significant increases were observed in comfort, visual quality, and overall satisfaction. The results of the study on the back-surface toric designs confirmed

this finding; median comfort an median wearing time increased significantly after changing from spherical scleral lenses to the toric designs (from 7 to 8; range, 1-10) and from 14 to 16 hours, both $P<0.001$, n=27 eyes).[14] Because of the more balanced distribution of pressure on the sclera, the back-surface toric designs may be less stressful to the eye and more easily tolerated than the spherical designs.

Several aspects may explain the discrepancy between findings on the basis of the interpatient comparison of the results of the questionnaire. The back-surface toric designs included complicated spherical lenses that were switched to these new designs, and the relatively recent availability of these new designs means that the patients have only short experience with them. It is the authors' experience that the wearing times increase, whereas the number of breaks and insertion problems decrease in the first half year of receiving a scleral lens. In this study setup, it was not possible to investigate differences between the two designs at the same lens age in the same patient. Prospective research on homogenous groups in the longer term therefore may be recommended.

In conclusion, modern materials, fitting techniques, designs, and production methods have added an extended role of scleral lenses in the management of several corneal abnormalities. The availability of four types of scleral lenses has enabled more precise scleral lens fitting. Optimized physical fitting of back-surface toric scleral lenses with toric bulbi resulted in greater patient satisfaction. In the interview, patients reported significant improvements in visual quality, comfort, and overall satisfaction with their scleral lenses.

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Chapter 6

Medical applications and outcomes of bitangential scleral lenses

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Abstract

Purpose: To evaluate the clinical results of a new scleral lens design with a bitangential (nonrotationally symmetrical) periphery.

Methods: All the necessary data were obtained during the one-year study period. The bitangential scleral lenses were fitted and monitored according to a standardized fitting methodology. They were cut by precise submicron lathing from high-oxygen-permeable materials (including 10 scleral lenses from Menicon Z material). Subjective performance, visual acuity and scleral lens-fitting characteristics were recorded after a median of 9.4 weeks (range, 3 weeks to 1 year).

Results: Diagnoses in the 213 eyes (in 144 patients) were keratoconus (n=121 eyes; 56.8%), ocular surface diseases (n=31 eyes; 14.6%), penetrating keratoplasty (n=29 eyes; 13.6%), and other forms of irregular astigmatism (n=28 eyes; 13.1%). Many patients (164 lenses; 77.0%) gave high ratings for comfort. The most common diameter was 20.0 mm (162 lenses; 76.1%) (range, 18.5 to 21.5 mm).
Median decimal best-corrected visual acuity with the bitangential scleral lenses was 0.8 (equivalent to Snellen 20/25) (range, 0 to 1.5). Most bitangential scleral lenses showed good fitting characteristics: optimal values were seen for lens movement (208 lenses; 97.7%) and lens position (208 lenses; 97.7%). Median central corneal clearance was 0.2 mm; clearances differed in the four peripheral directions. The median stabilization axis was 140 degrees (range, 0 to 180 degrees) in the right eyes and 60 degrees (range, 0 to 180 degrees) in the left eyes.

Conclusions: The bitangential scleral lens-fitting and performance characteristics were clear and effective for the health professional and the patient. The high-oxygen-permeable material Menicon Z may, in theory, be of benefit to corneas with a high oxygen demand.

Introduction

Scleral contact lenses have become increasingly popular among eye care practitioners who fit patients for medical indications. A scleral lens has various unique advantages, such as the retention of a precorneal fluid reservoir that affords simultaneous corneal hydration and optical correction of the irregular corneal surface. The rigidity of the material provides optical correction and mechanical protection. As a result, scleral lenses are effective in the management of irregular, fragile and diseased corneas as well as dry eyes. Keratoconus and other forms of irregular astigmatism comprise the major group of indications.

The clinical application of scleral lenses began with the work by Fick[1] and Muller[2] in the 1880s. Since then, diagnostic trial lens fitting, high-oxygen-permeable materials, and technological innovations in design and manufacturing have extended the use of scleral lenses.

Ezekiel[3] evaluated the use of gas-permeable scleral lenses in 1983 and reported greater acceptability and comfort with the oxygen-permeable scleral lenses than the polymethyl methacrylate (PMMA) versions. Further development of materials with high gas permeability has led to better performance of scleral lenses.[4-12] In 2006, Visser et al.[13-15] reported that the availability of toric scleral lenses enabled more precise scleral lens fitting and resulted in greater patient satisfaction. More recently, several reports on the use of rotationally symmetrical scleral lenses as well as toric and quadrant-specific scleral lens designs have illustrated the renewed interest in these devices by health professionals and industry.[16-20]

Van der Worp et al.[21] reported findings that have important clinical consequences on the fitting and design of scleral lenses. They found that toricity was more pronounced in the scleral than in the limbal area, irrespective of the toricity of the cornea. This suggests that nonrotationally symmetrical scleral lenses might be preferable to rotationally symmetrical scleral lenses. They also showed that, in most cases, the shapes of the limbus and anterior sclera were tangential rather than curved. On the basis of these findings, they concluded that when fitting scleral lenses, the use of tangential angles, rather than curves, may be appropriate in the majority of cases.[21,22]

This body of information formed the starting point to design a new scleral lens with a bitangential (nonrotationally symmetrical) periphery. The tangential periphery aims to enable gentle positioning on the scleral surface, increased fitting tolerance, and optimal centration. We found one earlier reference to tangential fitting in the Feincone Contact Lens Series described by Feinbloom[23] in the 1940s. The object of their tangential fitting was to reduce the adhesive pressure on the eye, to achieve greater tolerance, and to prolong the daily duration of use.[23,24]

The adjustable flat or steep meridian of this bitangential scleral lens design aims to distribute the lens pressure more equally over the sclera and improve the scleral lens fit, with less risk of air bubble formation behind the lens, or local blanching of the conjunctival scleral vessels. The latter disadvantages occur with rotationally symmetrical scleral lenses fitted to toric or irregular anterior scleral surfaces, because the edges are locally too flat or too steep.
This study evaluated the clinical findings with the bitangential scleral lens design.

Methods

All the scleral lenses applied in this study were fitted diagnostically with trial lenses, according to our standardized fitting methodology. During this fitting procedure, a trial lens was selected by evaluating the corneal and scleral profile macroscopically and with slit lamp examination. The fitting set consisted of 35 trial lenses with a diameter of 20.0 mm. If a trial lens did not fit correctly, it was replaced by a trial lens with the correct fit, which was then used to determine the exact size of the five parameters: sagittal depth, central radius (BCR), tangent angle of the flattest meridian of the scleral part, tangent angle of the steepest meridian of the scleral part, and total lens diameter. Fitting was based on resting the lens on the external sclera and vaulting over the cornea and limbus. An ideal lens was characterized by well-balanced haptic bearing, gentle movement of the lens with the push-up test and adequate corneal and limbal clearance. The desired apical clearance was about 0.2 mm, but varied according to the diagnosis or circumstances (Figure 1). Insufficient clearance (corneal touch) should be avoided, because it would cause mechanical pressure on the cornea, which might disturb the corneal physiology and decrease comfort and tolerance. However, excessive clearance (>0.5 mm) would make it more difficult to insert the lens without air bubbles. In eyes that tend to accumulate debris behind the lens, a smaller sagittal depth needs to be chosen because an increased volume of cloudy clearance will directly affect the patient's visual acuity (VA). In contrast, a larger sagittal depth may be necessary in eyes that are prone to progressive ectasia. Furthermore, the cornea may have so many irregularities that the sagitta has to differ locally, for example, in tilted transplants.

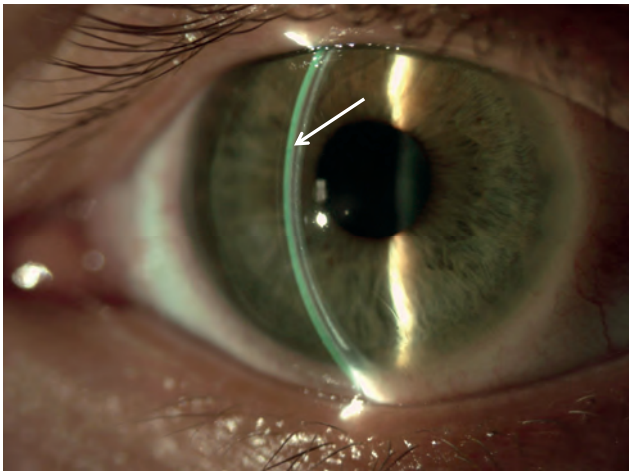

Figure 1. Apical clearance.

Data were gathered during the regular check-up visits between April 2011 and April 2012. One data set per patient was used for our analyses. We selected the data from the check-up visit in which the scleral lens had been worn for the longest duration (range, 3 weeks to 12 months). Lenses had been fitted or refitted at the scleral lens clinics at Visser Contact Lens Practice. All the patients who had been wearing one or two bitangential scleral lenses for at least 3 weeks and who gave informed consent (or their legal representatives in the case of minors) took part in the study. They had been referred to the clinic by their ophthalmologist on account of keratoconus, penetrating keratoplasty, other forms of irregular astigmatism, ocular surface disease (OSD), or other indications. The scleral lenses were being worn on a daily basis. Patients were instructed to clean, wet, and disinfect their scleral lenses using standard rigid gas-permeable lens solution systems. They were also advised to fill the lenses with unpreserved saline or the more viscous alternative, unpreserved sodium carboxymethyl cellulose 1.0% (Cellumed; Allergan Pharmaceuticals, Westport, Ireland). The latter was especially recommended in patients who consistently had air bubbles trapped behind the lens on insertion.

We recorded sex, date of birth, and diagnosis. Patients were asked to rate the comfort of their lenses on a five-point scale, which ranged from 1 (very poor) to 5 (excellent). The best-corrected visual acuity (BCVA) (in decimal form) was determined, as well as the over-refraction. To convert Snellen VA into decimal VA, the numerator must be divided by the denominator. Thus, a result of 20/25 is equivalent to the decimal score of 0.8.

Lens-fitting characteristics were assessed during the routine slit lamp examination. Corneal and limbal clearances were estimated in millimeters in five positions: central, superior,

inferior, nasal, and temporal. This was done using visual approximation based on the thickness of the cornea and the scleral lens; thickness of a trial lens = 0.4 mm. Lens movement was determined with the push-up test and graded according to our own system, which ranged from -2 (no lens movement) to +2 (excessive lens movement).[14] The position of the lens could be marked as central, or grade 1 (acceptable), or grade 2 (undesirable) decentration in a nasal, temporal, superior, or inferior direction. The stabilization axes were measured and recorded in degrees.

The new scleral lens design was realized in cooperation with NKL Contactlenzen (Emmen, the Netherlands) (Figure 2). It is defined by a front optical zone of 9.5 mm, a spherical back optical zone of 10 mm, and a midperipheral zone that vaulted the limbal area. The midperipheral zone has a width of 2 to 3 mm, depending on the overall lens diameter. This zone is smoothly connected to the optical zone and the linear alignment zone. The linear alignment zone is connected to the edge by an edge curve, which supplies extra edge clearance. The linear alignment zone is described by two meridians with different tangential angles to enable gentle application to the sclera. A large tangential angle implies a steeper haptic, whereas a smaller angle leads to a flatter scleral fit. In this way, two adjustable meridians are achieved: a flat and a steep meridian. These two different meridians of the linear alignment zone are 90 degrees apart and make the back-surface nonrotationally symmetrical, a so-called toric surface. The flattest meridian was marked with two engravings (Figure 3). The stabilization axis could be measured by projecting a narrow beam from the slit lamp parallel to the engravings on the scleral lenses. The axis could then be read from the protractor.

Parameters could be chosen independently at the request of the fitter. Each lens was engraved with a code that matched the parameters of the lens. Power range, including cylinders, was unlimited. The bitangential scleral lenses were cut by precise submicron lathing from high-oxygen-permeable materials. The materials used in this study were: Boston Equalens II (Oprifocon A, Dk 85), Boston XO (Hexafocon A, Dk 100), Boston XO2 (Hexafocon B, Dk 161), and Menicon Z (Tisilfocon A, Dk 189). Dk of the first two materials was listed following the Polarographic ISO/Fatt method, whereas the latter two materials were listed following the non-edge-corrected ISO/Fatt method. Boston materials were manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA, whereas the Menicon Z material was produced by Menicon Co. Ltd., Nagoya, Japan. At the time of this study, only a very limited amount of the Menicon Z material was available.

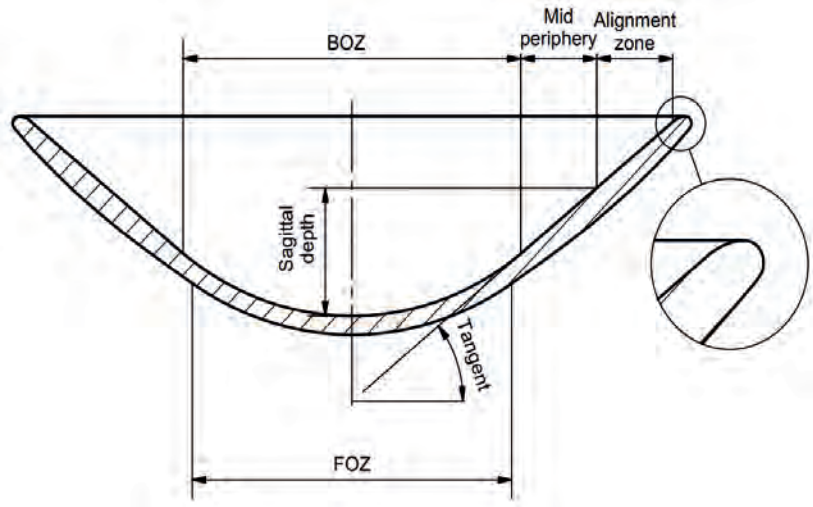

Figure 2. Bitangential scleral lens design.
BOZ = back optic zone, FOZ = front optic zone.
(courtesy of B.J.J.J. van der Linden, with permission)

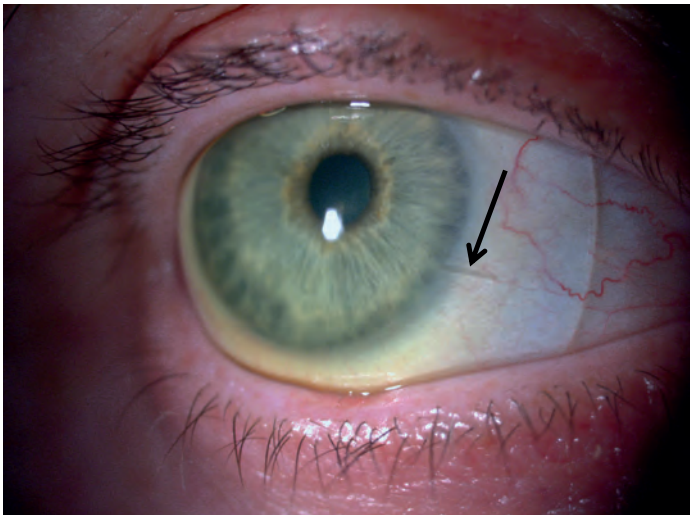

Figure 3. Engravings on the bitangential scleral lens.

Results

Evaluation was performed after a median of 9.4 weeks of wearing the new design and ranged from 3 weeks to 1 year.

Demography

A total of 144 patients (213 lenses) were evaluated in this study. They were composed of 80 (55.6%) males and 64 (44.4%) females. Bitangential scleral lenses were fitted bilaterally in 69 patients and unilaterally in 75 patients. The distribution of right and left eyes was almost equal: 108 right eyes and 105 left eyes. Mean age was 47.7 years (range, 11 to 86 years) (Figure 4).

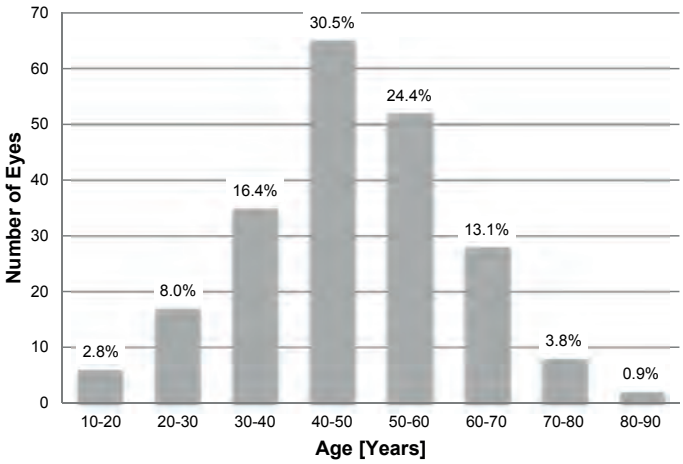

Figure 4. Age distribution (n=213 eyes).

Diagnoses

In this study, we categorized the diagnoses into five main groups (Table 1). The most common diagnosis was keratoconus (121 eyes; 56.8%). In the OSD group, there were eyes with sicca problems caused by several factors (keratitis sicca, Sjögren syndrome, lagophthalmos, neurothropic) and also eyes with recurrent corneal erosions. Irregular astigmatism included eyes with scarring related to several forms of keratitis or trauma and various corneal disorders with irregular corneal shapes, such as pellucid marginal degeneration, ectasia after refractive surgery, and Terrien marginal degeneration. The category “other diagnoses” consisted of high myopia, high astigmatism (>4 diopters), and ptosis.

Table 1. Diagnoses.

Diagnoses	No. of eyes, n (%)
Keratoconus	121 (56.8)
Ocular surface diseases	31 (14.6)
Penetrating keratoplasty	29 (13.6)
Irregular astigmatism	28 (13.1)
Other	4 (1.9)
Total	213 (100)

Comfort

The median score for scleral lens comfort was 4. The highest scores of 4 and 5 were given for 164 lenses (77.0%). Scores of 1, 2, and 3 were given for nine (4.2%), seven (3.3%), and 33 (15.5%) lenses, respectively.

Visual Acuity

Visual acuity outcomes are shown in Figure. 5. The decimal BCVA with the scleral lens was 0.8 (equivalent to Snellen 20/25) or better in 134 eyes (62.9%). Median decimal BCVA with the scleral lenses was 0.8 (range, 0 to 1.5). Lower BCVA outcomes occurred especially when the scleral lens had a more therapeutic than visual function, for example, as protection in patients with severe keratitis sicca and patients with scarring after herpes simplex keratitis. Poorer results were also encountered in patients with very progressive keratoconus, after keratoplasty, and in a patient with irregular astigmatism and secondary nystagmus.

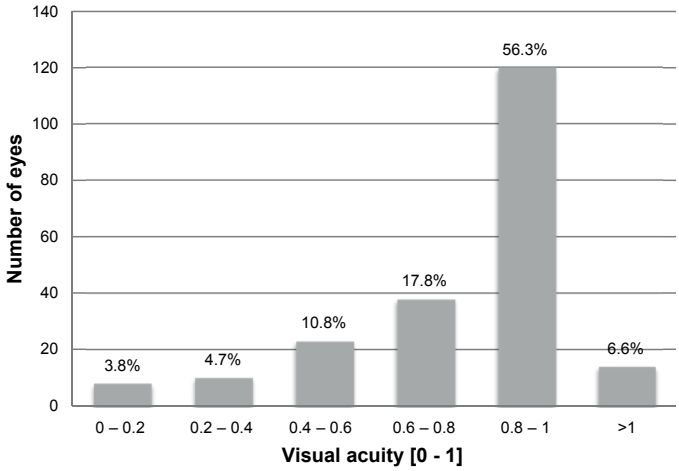

Figure 5. Visual acuity (n=213 eyes).

Scleral Lens Characteristics

Mean overall diameter of the scleral lenses was 19.9 mm; a total of 162 lenses (76.1%) had a diameter of 20.0 mm. In 40 eyes (18.8%), smaller diameters were fitted (range, 18.5 to 19.5 mm), whereas in 11 eyes (5.2%), larger diameters were fitted (range, 20.5 to 21.5 mm).

Distributions of the materials used in this study were Boston XO2 in 143 eyes (67.1%), Boston XO in 36 eyes (16.9%), Boston Equalens II in 24 eyes (11.3%), and Menicon Z in 10 eyes (4.7%).

Scleral Lens-Fitting Results

The scleral lens movement was graded as desirable (acceptable to optimal values) in 208 eyes (97.7%). Undesirable movement was encountered in 5 eyes (2.3%): excessive mobility in 2 eyes and no lens movement in 3 eyes (Table 2).

Table 2. Movement of the bitangential scleral lens (n=213 eyes).

Grading	Explanation	No. of eyes, n (%)
-2	No movement	3 (1.4)
-1	Reduced movement acceptable	22 (10.3)
0	Optimal movement	162 (76.1)
1	Increased movement acceptable	24 (11.3)
2	Excessive movement unacceptable	2 (0.9)

Almost all of the lenses showed good positioning: acceptable to central in 208 lenses (97.7%). Decentration of the scleral lens was observed most frequently in the inferior, temporal, or inferotemporal position (Figure 6).

Median central corneal clearance was 0.2 mm (range, 0.05 to 0.6 mm). Limbal clearances differed in the four positions: the inferior and temporal values were higher than the superior and nasal values (Figure 7). Results in the right and left eyes were fairly similar.

The stabilization axes of the flattest meridians in the right and left lenses are shown in Figure 8. In the right eyes, the median stabilization axis was 140 degrees (range, 0 to 180 degrees); in the left eyes, it was 60 degrees (range, 0 to 180 degrees). Right lens median values fell in the area with the most stabilizations. This was not the case with the left lenses. The stabilization values had a different distribution (over two quadrants around the horizontal 0-180-degree axis rather than over one quadrant) (Figure 8).

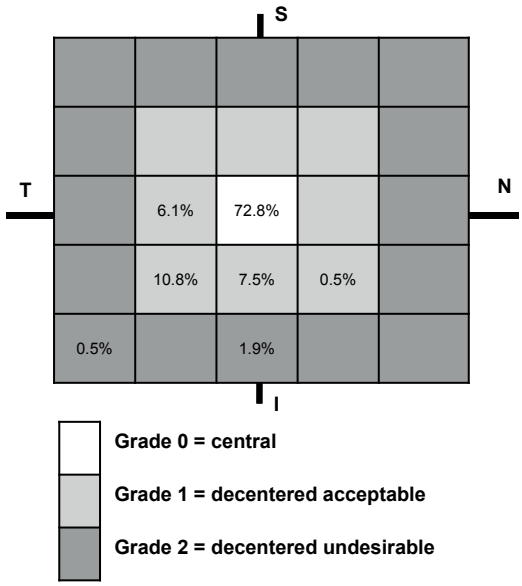

Figure 6. Centration of the bitangential scleral lens (n=213 lenses).
I = inferior, N = nasal, S = superior, T = temporal.

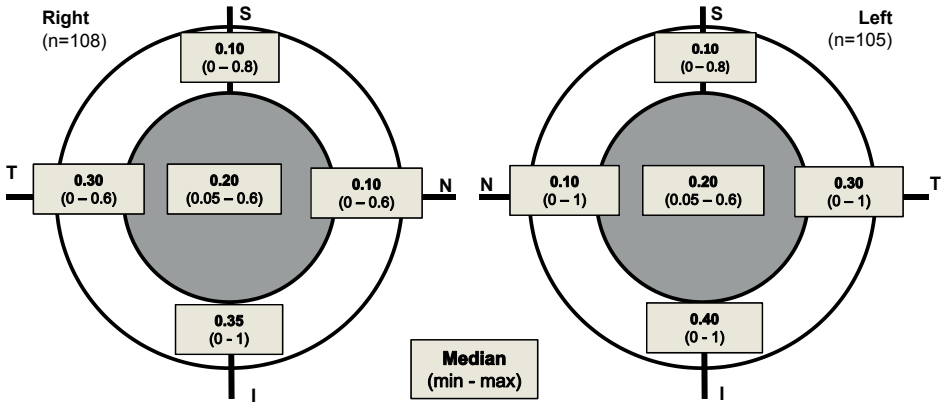

Figure 7. Clearance (median in millimeters).
I = inferior, N = nasal, S = superior, T = temporal.

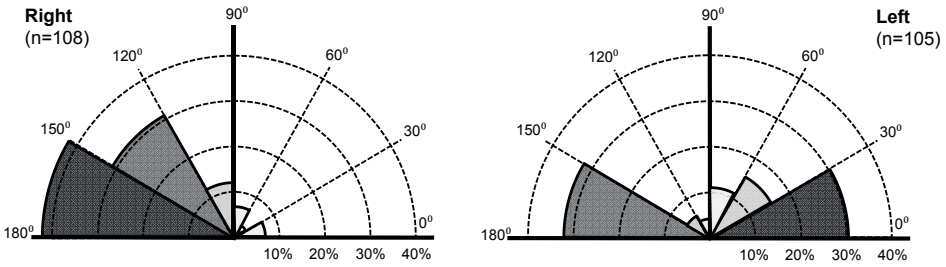

Figure 8. Stabilization axes of the flattest meridians.

Discussion

This study addressed the clinical results of the use of bitangential scleral lenses in 144 patients (213 eyes), with a variety of ocular disorders. We followed the patients in the first year after they had been fitted at our practice. Evaluations were performed on one or two lenses per subject because there was no comparison group and it was unlikely that the eyes of these patients were correlated. It was beyond the scope of this study to compare the performance of different types of scleral lens design. Further studies on the different types are necessary to reveal differences between the lens designs.

The largest diagnostic category was keratoconus, followed by OSD, penetrating keratoplasty, and other forms of irregular astigmatism. This distribution was consistent with that in other reports on scleral contact lenses. Corneal irregularity therefore forms a leading indication for scleral lens fitting.[6,8,9,14,19,25-28] Another well-described application for scleral lenses is OSD (mainly keratitis sicca).[6,28-37] Patients often experience relief or resolution of symptoms, such as dry eyes, irritation, pain, and photophobia, when wearing scleral lenses.

In our study group, age ranged from 11 to 86 years; two patients were younger than 16 years (three eyes). Gungor et al.[38] studied 31 patients (47 eyes) in the pediatric age group (age range, 7 months to 12.92 years), with a wide range of ocular surface and refractive disorders and observed clear benefits of scleral lenses. Rathi[39] reviewed 20 eyes in a group of patients of 16 years or younger who had received scleral contact lenses. He concluded that these lenses were beneficial to pediatric patients but that fitting was challenging and required considerable time and patience from the parents and the clinician. In our own experience, children are generally highly motivated and show good compliance.

Our study group also included elderly patients for whom scleral lens handling might be challenging, but scleral lenses are robust and dimensionally stable, which is advantageous for elderly and less dextrous patients.

All the scleral lenses applied in this study were fitted diagnostically with trial lenses following our standardized fitting methodology. Schornak and Patel[40] investigated the correlation between the anterior corneal contour parameters and the base curve of scleral lenses and found only a weak predictive relationship. They concluded that, at present, the diagnostic approach seems to be the most efficient method to fit scleral lenses.[40] However, new developments in commercially available technology to measure scleral topography might become helpful in the fitting process.

Material selection was done individually. In general, the more highly oxygen-permeable materials were preferred by the scleral lens fitter. However, exceptions were made in patients who, for instance, were known to have increased protein deposits or scratched lenses. In these cases, the lower oxygen-permeable materials were advisable because they are less prone to deposits and scratching. Based on calculations, Michaud et al.[41] recommended the prescription of scleral lenses with the highest Dk values available to minimize corneal hypoxia. As scleral lenses are typically thicker than corneal lenses, their relative oxygen transmissibility is lower. This applies especially to lenses with high refractive powers, which increase the central or the peripheral thickness of the optical zone of the scleral lens.[41] Weismann and Ye[42] took another point into consideration, namely, that a diseased cornea may have larger or smaller oxygen requirements or possibly a larger or smaller response to hypoxia. They concluded that acceptable values of tear oxygen tension can be expected beneath the scleral lens (of 100 Fatt Dk units) under open eye conditions.[42] The gas permeability of the Menicon Z material exceeded the recommendations made by Michaud et al.[41] and should therefore provide maximum benefit for corneas that require more oxygen, for example, eyes with long-term transplants and resulting low endothelial cell counts. This hypothesis still needs to be tested. Menicon Z material did not become available until the end of our study. Therefore, it was only applied to 10 eyes.

The good performance of the scleral lenses used in our study was first expressed in the high comfort scores given by the patients: 77.0% of the lenses were rated with the highest scores of 4 or 5.

Several developments over the past few years have led to increased patient satisfaction with their scleral lenses. The introduction and use of gas-permeable materials have made scleral lenses more comfortable to wear.[3,6,8,9,43] Previously, we reported that back-surface toric scleral lenses gave greater comfort than the back-surface spherical scleral lenses. Furthermore, our study on modern scleral lenses revealed high patient satisfaction with all the modern scleral lens designs (toric and spherical). Generally, scleral lenses were more comfortable than the patients' former type of correction (e.g., spectacles or other contact lenses).[13,15]

Improvements in VA compared to spectacle correction constitute the greatest benefit of scleral lens fitting in the majority of patients. Best-corrected VA often improves enormously, as has been described in several studies.[9,14,16,19,26-28,44] The best VA results were observed in the group with irregular corneal topography. When scleral lenses are fitted for therapeutic reasons, changes in VA are often less pronounced because, in this group of patients, the main goals are protection, tear conservation, and/or pain relief.[14] In the current study, the median VA was 0.8, which was in line with previous findings.

Correct lens fitting is essential to avoid complications. In an earlier study, we found that nonoptimal lens fitting values formed a frequent reason to recommend lens refitting.[14]

The present study showed optimal lens fitting characteristics in the majority of eyes. Variations in clearance were in accordance with the lens position: greater clearance typically occurred in the most common directions of decentration, namely, the temporal and inferior directions.

It was remarkable that the median stabilization axis values of the lenses were very similar to those in a previous study by Visser et al.[13] In the present study, the median in the right eyes was 140 degrees (range, 0 to 180 degrees) compared to 137 degrees (range, 30 to 180 degrees) in our earlier study; in the left eyes, it was 60 degrees (range, 0 to 180 degrees) compared to 47 degrees (range, 0 to 170 degrees) in our previous study.[13] As the stabilization values in the left eyes were distributed over two quadrants around the horizontal 0- 180-degree axis rather than over one quadrant, the median value did not fall within the area with the most stabilization values (Figure 8).

In this study, the most frequently used scleral lens diameter was 20.0 mm. This was not surprising because our routine fitting lenses have a diameter of 20.0 mm. Some patients seemed to need a larger or smaller diameter during fitting, so the most appropriate diameter was chosen. This study revealed that reductions in size (from the standard size of 20.0 mm) were more common than enlargements. Other studies also reported the application of different sizes. These lenses have been referred to as Semi-Scleral, Mini-Scleral, and Cornea-Scleral in the literature, and there is a continuum in diameter between these and scleral lenses.[35]

The Scleral Lens Education Society has developed a classification system that defines scleral lens types on the basis of their size: Semi-Scleral (12.5 to 15.0 mm), Mini-Scleral (15.0 to 18.0 mm), and Large-Scleral (18.0 to 25.0 mm).[22,45] Such clear categories will make it considerably easier to compare groups of patients with scleral lenses in future studies.

Renewed interest in the scleral profile and scleral lenses has resulted in new scleral lens designs, which complements and improves scleral lens practice.

This study revealed that the bitangential scleral lens fitting and performance characteristics were clear and effective for the practitioner and the patient. The tangential and nonrotationally symmetrical periphery achieved central and stable fitting of the scleral lens, which resulted in high comfort scores. The high-oxygen-permeable material Menicon Z may, in theory, be of benefit to corneas with a high oxygen demand.

The new scleral lens design with a bitangential (nonrotationally symmetrical) periphery was very beneficial to patients with OSDs and irregular corneas secondary to disease or previous surgery.

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Chapter 7

Scleral lens tolerance after corneal crosslinking for keratoconus

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Abstract

Purpose: Subjective and objective evaluation of scleral lens tolerance and fitting before and after corneal crosslinking (CXL) for progressive keratoconus.

Methods: In this prospective cohort, evaluations were made of 18 unilateral eyes in patients who underwent CXL and had been wearing scleral lenses before the procedure. All the patients gave informed consent; they were able to cooperate with the study, were eligible for CXL, had been wearing well-fitting scleral lenses for at least 3 months, and had no other active ocular disease. Data were collected before and 1 year after CXL. Outcome measures were changes in clinical and subjective scleral lens performance. The following components were studied: scleral lens corrected distance visual acuity, scleral lens specifications, scleral lens fit, wearing time, and subjective measures on visual analog scale questionnaires (1 to 100 mm).

Results: There was no significant change in scleral lens corrected distance visual acuity (P= 0.632). Sixty-one percent of eyes needed a scleral lens fit and/or power change. Wearing time (median, 16 hours per day) and subjective tolerance were found to be stable.

Conclusions: Scleral lens tolerance after CXL appeared to be stable.

Introduction

Keratoconus is a noninflammatory corneal disease, characterized by cone-shaped changes in the corneal curvature, which usually results in visual loss.[1] Depending on the severity, a spectrum of correction options are available. In the early stages, spectacles, soft lenses, or silicone hydrogel lenses can be prescribed. In more progressive cases, custom-designed soft, piggyback, hybrid or rigid-gas permeable corneal contact lenses can be applied. Scleral lenses are usually indicated in cases of corneal contact lens intolerance, secondary clinical indications (such as dry eyes), and advanced disease, or to prevent corneal scarring.

Scleral lenses have the unique property of vaulting the cornea and can therefore be fitted to eyes with marked corneal irregularity. The constant precorneal fluid reservoir neutralizes the irregular astigmatism and simultaneously hydrates and protects the corneal surface from exposure and the friction of blinking. Keratoconus is one of the most common indications for scleral lens fitting.[2-6]

The first clinical application of scleral lenses was described by Fick and Muller in the 1880s.[7,8] Since then, scleral lens design and materials have undergone several milestone developments. The availability of trial fitting sets and gas-permeable materials and the development of toric scleral lens designs and, more recently, tangential scleral lenses have improved the fitting process and thus patient comfort and satisfaction.[2,3,6, 9-14]

Other available treatment options for keratoconus are corneal ring segments (in cases with stable keratoconus and contact lens intolerance)[15] or corneal transplantation (in cases with severely advanced keratoconus with decreased vision and/or scarring).[16]

In progressive keratoconus, corneal crosslinking (CXL) with epithelial removal can be applied to stabilize the cornea. CXL is a noninvasive medical treatment that uses a combination of ultraviolet A (UV-A) light and riboflavin (vitamin B_2) eye drops. After CXL, corneal biomechanical stability increases by 70%.[17-19] Corneal flattening and visual improvement have been described after CXL. Furthermore, it is known that after CXL with epithelial removal, corneal sensitivity can be reduced, owing to not only the corneal abrasion but also to the use of riboflavin and UV-A.[20]

Unfortunately, the various CXL studies do not appear to apply a consistent approach in relation to contact lens or scleral lens wear. This makes it difficult to accurately compare lens fitting results after CXL, because refraction and corneal curvature are often influenced by lenses, especially corneal contact lenses.[21] In contrast, scleral lenses vault the cornea and have no mechanical contact with it. Therefore, hypothetically, scleral lens wear should

not be affected by corneal curvature changes caused by CXL. To our knowledge, no research has been performed on scleral lens wear after CXL.

This study aims to compare scleral lens tolerance and fitting before and after CXL using clinical and subjective measures. This article forms a backing to provide advice and information for keratoconic patients with scleral lenses who are considering CXL. It is important to guide their future expectations and indicate the potential need to refit the lens post-CXL.

Methods

In this prospective cohort, a total of 18 eyes of 18 patients with progressive keratoconus who were scheduled for CXL and wore scleral lenses were evaluated.

Prospective data were collected on consecutively planned CXL treatments after approval by the Medical Ethics Committee of the University Medical Center Utrecht (UMCU). Written informed consent was obtained in accordance with the UMCU guidelines and the study was conducted in compliance with the Declaration of Helsinki.

Data were collected at the baseline visit (meaning ≤6 weeks before CXL) and at 1 year post-CXL. Inclusion criteria for this study were eligibility for CXL and scleral lens wear for at least 3 months prior to CXL. We excluded any subjects who were wearing poorly fitted lenses (in case of one or more grade 2 findings, Table 1), or were unable to cooperate, or had other ocular diseases.

Inclusion criteria for CXL were a clear central cornea, documented keratometric progression over 6 to 12 months, a minimum corneal thickness of 400 µm before UV-A irradiation, and no pregnancy or breastfeeding.

All the CXL procedures were performed by the same team at the Department of Ophthalmology of the UMCU using the UV-X system (Peschke Meditrade GmbH) (370 nm and 3 mW/cm^2) as described previously.[22] Both epithelium-off (n=15 eyes) and epithelium-on (n=3 eyes) techniques were applied.

Table 1. Scleral lens fitting characteristics.

	Grade -2 unacceptable	Grade -1 acceptable	Grade 0 optimal	Grade +1 acceptable	Grade +2 unacceptable
Central corneal clearance	Corneal contact	≤0.1 mm	0.1 to 0.3 mm	>0.3 mm to ≤0.5 mm	>0.5 mm
Limbal corneal clearance	Circumcorneal limbal contact	Circumcorneal <0.05 mm	0.05 to 0.2 mm	Circumcorneal >0.2 mm to ≤0.3 mm	Circumcorneal >0.3 mm
Scleral (haptic) fit	Circumcorneal blanching	Segmented/slight blanching	Scleral alignment	Slightly increased edge clearance	Increased edge clearance, with possible trapped air bubbles
Lens movement (push-up test)	Lens suction	Reduced	Gentle	Increased	Excessive
General lens fit			Optimal	Acceptable	Unacceptable
Front surface lipid deposits			Absent	Slight	Severe
Front surface protein deposits			Absent	Slight	Severe
Scratches			Absent	Slight	Severe

Epithelium-off CXL

The epithelium was removed using a blunt knife, and isotonic riboflavin 0.1% solution (Medio Cross) was instilled every 3 minutes for 30 minutes. When corneal thickness was less than 400 µm after riboflavin instillation, hypo-osmolar riboflavin 0.1% drops were instilled every 20 seconds for 5 minutes. When the required corneal thickness was reached, UV-A irradiation (UV-X 1000, Peschke Meditrade) was performed for 30 minutes, whereas isotonic riboflavin solution was reinstilled every 5 minutes. After the procedure, a balafilcon A bandage lens (Pure Vision, Bausch & Lomb) was placed.

Epithelium-on CXL

Ricrolin TE eye drops (SOOFT Italia) were instilled every 2 minutes for 15 minutes. Next, an eyelid speculum was placed and a silicone ring was positioned between the eyelids, which was filled with ricrolin TE and refilled when necessary to remain a ricrolin "pool" on the cornea. After 15 minutes, the silicone ring was removed, the cornea was rinsed with balanced salt solution, and pachymetry was measured. With an eyelid speculum in place, UV-A irradiation was performed during 30 minutes, whereas ricrolin TE solution was reapplied to the cornea every 5 minutes.

Patients with epithelium-off CXL received oral analgesics and all patients received antibiotic eye drops. Post-CXL, patients were requested to refrain from wearing their scleral lenses for 1 month. The keratoconus progression was halted at the 1-year follow-up in all our patients, regardless of treatment type.

Fifteen scleral lenses were fitted at the Contact Lens Service and three scleral lenses were fitted at external lens institutions. All the lenses were manufactured from high oxygen-permeable materials at three different laboratories: Procornea (12 bitoric (curved-designed) scleral lenses) (Eerbeek, the Netherlands); NKL Contactlenzen (3 bitangential designed scleral lenses) (Emmen, the Netherlands), and Microlens (3 bitoric (curved-designed) scleral lenses) (Arnhem, the Netherlands). The materials used in this study were Boston Equalens II (Oprifocon A, Dk 85 [Polarographic ISO/Fatt method]), Boston XO2 (Hexafocon B, Dk 161 [non–edge corrected ISO/Fatt method]) (both manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA, USA), and Tyro-97 (Hofocon A, Dk 97 [ISO/ANSI method) (manufactured by the Lagado Corporation, Englewood, CO), USA. All scleral lenses evaluated in this study had been fitted diagnostically with trial lenses and were being worn daily.

Our analysis was performed on the first eye of each patient who underwent CXL. Baseline visits took place between July 2010 and October 2012 and the 1-year follow-up took place between August 2011 and November 2013. Sex, date of birth, and lens history were noted. At these two visits, details were recorded of the origin of the scleral lens, scleral lens parameters (spherical power, cylindrical power, scleral zone, scleral toricity, sagittal depth, central radius (base curve radius, BCR), total lens diameter), average wearing time, and frequency of breaks from wearing the lens during the day. The scleral zone was described in either millimeters (radius) or degrees (tangent angle), depending on the type of scleral lens design (curved or tangential). To evaluate and compare these two different parameters, each was assigned a code that varied from -1 (12.25 mm or 47 degrees) to + 8 (14.50 mm or 38 degrees), where an increment of 1 was either 0.25 mm or 1 degree. The spherical equivalent (SE) as well as the required power adjustment in the case of a change in BCR were computed for all the eyes; this is further referred to as the ”SE with BCR adjustment.” A change in BCR of +0.05 mm resulted in a change in spherical power of +0.25 diopters. In addition, all the patients underwent decimal scleral lens corrected distance visual acuity (CDVA) assessment and slit lamp biomicroscopy assessment (to grade the lens fitting).

The scleral lens parameters of lenses fitted by external contact lens institutions were obtained from the scleral lens fitter. A previously described classification method was used and adjusted to the present standard to grade the various scleral lens fitting characteristics (Table 1). [2] Grade 0 was considered “optimal”; grade 1, “acceptable”; and grade 2, “unacceptable.”

At the end of the baseline visit and follow-up visit, patients were asked to complete a questionnaire on six specific topics: lens comfort, lens dryness, scleral lens visual quality, lens cleanliness, lens handling, and overall satisfaction with the scleral lens. Scores were obtained on a visual analog scale (VAS) with an axis from 0 mm (unacceptable performance) to 100 mm (excellent performance).

Spectacle CDVA (meaning without the scleral lenses) was evaluated retrospectively by chart review.

Statistics

After checking all the data, the data file was transferred to SPSS (IBM SPSS Statistics version 20.0 for Windows) for statistical analysis. The data were tested for normal distribution using the Shapiro-Wilk test for normality. The reported differences were normally distributed and were analyzed with the paired samples *t* test. A p value of less than 0.05 was considered statistically significant. Variables and series with a normal distribution were characterized

by mean and range. If one or more of the variables in a series did not show a normal distribution, they were characterized by nonparametric summary statistics: median and range. Decimal acuity was converted into logMAR units with the formula –log (decimal acuity). A *post hoc* power analysis for the logMAR scleral lens CDVA was performed for a paired samples *t* test (sample size of 18 eyes, with $\alpha = 0.05$ and an effect size of 0.6) and was estimated to be 0.79.

Results

All 18 patients (100%) returned for follow-up within the study period. Median follow-up was 12 months (range, 11 to 13 months), which was in accordance with the study protocol.

Demography

A total of 12 right eyes (67%) and 6 left eyes (33%) were evaluated. Our study group comprised 14 female subjects (78%) and 4 male subjects (22%); mean age was 28 ± 10 years (range, 15 to 48 years). Median total duration of contact lens use and/or scleral lens use was 66 ± 105 months (range, 5 months to 30 years). Median duration with the current scleral lens design was 9 ± 24 months (range, 3 to 88 months).

Visual Outcome and Scleral Lens Prescription

Visual acuity at baseline and the outcome at 1-year follow-up are listed in Table 2. No significant change was observed in logMAR scleral lens CDVA (*P*= 0.632). There was a wide range in outcomes of the scleral lens power units (Table 3). Spherical scleral lens power changed in 11 of the 18 eyes (61%): 8 eyes showed a hyperopic shift and 3 eyes showed a myopic shift. In 5 of the 10 eyes with a cylindrical prescription before CXL, the cylinder changed (50%): an increase occurred in 3 eyes and a decrease occurred in 2 eyes. The SE with BCR adjustment changed in 10 of the 18 eyes (56%).

At 1-year follow-up, spectacle CDVA (i.e., without scleral lenses) had improved by 0.17 logMAR (*P*= 0.011). Mean duration between the measurements at baseline and at 1-year post-CXL was 13 months (range, 11 to 17 months).

Table 2. Visual outcome with scleral lenses, 1 year after corneal CXL (n=18 eyes).

	Baseline visit	1-y follow-up	Difference	P value
LogMAR CDVA	0.22 (-0.18 to 0.69)*	0.03 (0.00 to 0.92)*	-0.26 (-0.64 to 0.69)* -0.03‡	0.632†
Decimal CDVA (Snellen CDVA)	0.8 (0.5 - 1.2)* (20/25 (20/40 to 20/16))	1.0 (0.4-1.0)* (20/20.5 (20/50 to 20/20))		

*Median (range).
†Paired samples *t* test.
‡Mean.
CDVA, corrected distance visual acuity with scleral lenses.

Table 3. Scleral lens prescription.

	Baseline visit	One year follow-up
Spherical power (n=18 eyes)	+1.75 (-4.00 to +6.00)	+2.13 (-2.50 to +6.00)
Cylindrical power (n=10 eyes)	-1.25 (-2.50 to -0.75)	-1.25 (-2.00 to -0.75)
SE corrected for central radius differences (n=18 eyes)	+ 1.50 (-4.00 to +5.38)	1.56 (-3.75 to +5.38)

All values are median (range).

Scleral Lens Specifications

In 12 of the 18 eyes (67%), the scleral lens needed to be replaced during follow-up and the same type of design (same manufacturer) was used. Reasons included routinely scheduled lens replacements with unchanged lens parameters. No replacements were necessary in the remaining 6 eyes (33%). Outcomes of scleral lens parameters at both visits are listed in Table 4. One year post-CXL, individual lens evaluation showed a change in scleral radius, scleral toricity, sagittal depth, BCR, and total lens diameter in 9 (50%), 6 (33%), 7 (39%), 3 (17%), and 3 (17%) eyes, respectively.

Table 4. Scleral lens specifications (n=18 eyes).

	Baseline visit	1-y follow-up
Scleral radius, code	2 (-1 to +8)*	2 (-1 to +8)*
Scleral toricity, code	2 (1 to 4)†	2 (0 to 4)†
Sagittal depth, mm	4.14 (3.67 to 4.67)*	4.17 (3.67 to 4.50)*
BCR, mm	8.10 (7.40 to 8.60)†	8.20 (7.40 to 8.60)†
Total lens diameter, mm	20.0 (19.0 to 21.0)†	20.0 (19.0 to 21.5)†

*Mean (range).
†Median (range).

Scleral Lens Fitting Results

All scleral lens fitting components were graded as optimal or acceptable (grade 0 or 1) at the two visits. The majority of scleral lenses showed grade 0 both times (Table 5). Scleral lens deposits and scratches were also optimal or acceptable. At baseline and at the 1-year follow-up, protein deposits were absent in 11 (61%) lenses and 8 (44%) lenses, respectively. Lipid deposits were absent in 11 (61%) lenses and 15 (83%) lenses, respectively. The remaining lenses had slight (grade 1) protein or lipid deposits. At both visits, 8 (44%) lenses did not show any scratches, whereas 10 (56%) lenses where slightly scratched.

Table 5. Scleral lens fitting (n=18 eyes).

	Baseline visit, n (%)					1-y follow-up, n (%)				
Grade	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Central corneal clearance	0	2 (11)	14 (78)	2 (11)	0	0	0	16 (89)	2 (11)	0
Limbal corneal clearance	0	2 (11)	16 (89)	0	0	0	2 (11)	15 (83)	1 (6)	0
Scleral (haptic) fit	0	4 (22)	12 (67)	2 (11)	0	0	0	16 (89)	2 (11)	0
Movement	0	4 (22)	13 (72)	1 (6)	0	0	3 (17)	15 (83)	0	0
General lens fit	0	0	14 (78)	4 (22)	0	0	0	18 (100)	0	0

Wearing Time

Scleral lenses were worn for a median of 16 hours per day at both visits (range, 10 to 17 hours at the baseline visit; range, 10 to 18 hours at 1-year follow-up). The number of patients who needed a break from their scleral lens wear during the day remained approximately identical; the number was 5 (28%) patients at baseline and 4 (22%) patients at 1 year follow-up.

Subjective Performance

The outcomes of the patient questionnaire (VAS 0 to 100 mm) are shown in Table 6. Small decreases were seen in comfort, lens dryness, lens cleanliness, lens handling, and overall satisfaction. Subjective scleral lens visual quality showed a slight increase.

Table 6. Subjective outcomes (VAS questionnaires 0 to 100 mm) (n=18 eyes).

	Baseline	1-y follow-up
Comfort	84 (56–100)	79 (65–95)
Lens dryness	79 (45–98)	73 (25–95)
Visual quality	69 (25–96)	75 (24–95)
Lens cleanliness	76 (57–96)	68 (34–96)
Lens handling	85 (56–98)	83 (44–100)
Overall satisfaction	84 (65–98)	81 (57–100)

All values are mean (range).

Discussion

This study evaluated scleral lens tolerance and fitting before and 1 year after CXL in patients with progressive keratoconus. Our main finding was that CXL did not affect scleral lens tolerance.

To our knowledge, this is the first study on scleral lens wear after CXL. In theory, scleral lens wear should not be affected by corneal curvature changes due to CXL, because scleral lenses vault the cornea and therefore do not make any mechanical contact with the cornea (in contrast with corneal contact lenses).

In our patient group, the objective and subjective performance outcomes of the scleral lenses were not affected by variations in scleral lens conditions. Fitting and surface quality (deposits and scratches) of all the scleral lenses were optimal or acceptable at baseline and follow-up. Furthermore, patients did not change to lenses of another type of design (and manufacturer) during the study.

Our study had limitations in terms of a small sample size and the lack of a control group. However, our findings can be considered valuable owing to the prospective study design, which included both analyses and observed results of subjective and objective data before and after CXL. Further research with a larger sample size and a control group is recommended. Although both epithelium-on and epithelium-off CXL procedures were applied, data were analyzed in this case series, because the keratoconus progression was halted at the 1-year follow-up in all our patients, regardless of treatment type.

Individual scleral lens fitting parameters (such as scleral radius, scleral toricity, sagittal depth, BCR, and total lens diameter) changed in 17 to 50% of the cases at 1-year follow-up. In addition, the cylindrical prescription changed in 50% of the eyes, whereas the spherical scleral lens power changed in 61% of the eyes. Variations in scleral lens parameters over time were expected and could form a part of these numbers. It is common practice to

regularly replace and/or refit scleral lenses in view of potential changes in lens power, corneal or scleral lens fitting, or a decline in scleral lens conditions. Visser et al. found that scleral lens refitting was recommended in 21% of patients who returned for scheduled follow-up. They suggested replacing the lens at intervals of 2 to 3 years.[2] This replacement interval seems to have been reduced over the past few years to 1.5 to 2 years, to guarantee the quality and oxygen permeability of lens materials. Replacement intervals of scleral lenses vary widely from 1 year to several years.[23]

After CXL, patients should be advised to have their scleral lenses checked (and, if necessary, refitted), because some of the lens fitting parameters might have changed. Omitting the application of a necessary increase in the sagittal depth and/or BCR will directly affect the corneal vaulting of the scleral lens and may result in corneal touch. Mechanical stress on the cornea should be avoided.

In the current study, high median visual outcomes were observed before and after CXL, which was consistent with other studies on scleral lens application in patients with keratoconus. Segal et al.[5] reported a scleral lens CDVA of greater than or equal to 20/40 in 91% of the cases in their keratoconus group. Pullum et al.[4] reported that sclera lens CDVA in their primary corneal ectasia group peaked at 20/30, whereas Visser et al.[2] showed that the highest median increase in scleral lens CDVA occurred in eyes with keratoconus, namely 0.50 decimal acuity. Schornack and Patel[24] reported a median scleral lens CDVA of 20/20 in keratoconic eyes.

Consecutively, the 1-year post-CXL visual results were as follows: scleral lens CDVA remained stable, spectacle CDVA increased significantly, and subjective scleral lens visual quality showed an increasing trend. An explanation for the stable outcome of the scleral lens CDVA might be the small sample size, because the individual scleral lens CDVA outcomes varied widely. Moreover, as scleral lenses correct the total corneal irregularity, CXL effects (such as corneal stabilization and spectacle CDVA improvement) will not necessarily affect scleral lens CDVA. The significant spectacle CDVA improvement in this study is in line with other studies on CXL.[19,25]

Daily wearing time and the need for breaks to clean the lens(es) are indicators of scleral lens performance. In our series, the median wearing time of 16 hours per day was comparable with earlier studies that used a similar method to assess wearing time: Segal et al.[5] reported a mean wearing time of 16.2 hours a day and Visser et al.[12,13] showed a median daily wearing time of 16 hours. The continued good subjective tolerance of scleral lenses after CXL was demonstrated by comparable daily wearing times and the number of breaks during the day, as well as very small differences in comfort, lens dryness, lens handling, and overall satisfaction after 1 year.

In our study, we advised patients to discontinue their scleral lens wear for 1 month after the CXL procedure and to reevaluate the fitting before restarting scleral lens wear. There does not seem to be any consensus in the literature on the (temporary) discontinuation of contact lens wear after CXL.[21] Furthermore, to our knowledge, specific advice on scleral lens wear has not been reported at all. Discontinuation of scleral lens wear during the first month post-CXL did not seem to have any undesirable side effects in our series of patients. Future research into the minimally required discontinuation time would be of value to keratoconic patients who depend on their lenses for adequate daily functioning. Additionally, prospective research into the tolerance and stability of other types of contact lenses is recommended, especially in the case of corneal contact lenses, because of the potential role of decreased corneal sensitivity and corneal flattening after CXL.

In conclusion, objective and subjective scleral lens tolerance remained stable after CXL in this study. However, to maintain optimal and safe lens performance and avoid mechanical stress on the cornea, scleral lens fitting should be reevaluated after CXL, because scleral lens fitting parameters may have changed.

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Chapter 8

Scleral lens influence on corneal curvature and pachymetry in keratoconus patients

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Abstract

Objectives: To investigate the influence of full scleral lenses on corneal curvature and pachymetry in keratoconus patients.

Methods: In this intervention study, 20 eyes of 14 patients were measured by Scheimpflug imaging (Pentacam HR, Oculus) at two time points: directly and ≥1 week after scleral lens removal. Steep, flat and maximal keratometry (K_{steep}, K_{flat} and K_{max}) and optical pachymetry were analyzed. A generalized estimating equation analysis was performed to correct for paired eyes.

Results: Directly after scleral lens removal, all three curvature parameters were significantly flatter compared to ≥1 week after scleral lens removal. Average K_{steep} was 0.7 diopter (D) lower (P<0.001), average K_{flat} was 0.5 D lower (P=0.037) and average K_{max} was 1.1 D lower (P<0.001). Directly after scleral lens removal, average optical pachymetry was ±2.5% higher (P<0.001) compared to ≥1 week after scleral lens removal.

Conclusions: Although scleral lenses do not mechanically touch the cornea, curvature and pachymetry seem to be influenced by scleral lens wear in keratoconus patients. The duration of these changes remain unclear.

Introduction

Ectatic corneal disorders, such as keratoconus, often result in visual complaints related to the irregular cornea and resulting astigmatism. In mild to moderate disease, corneal contact lenses (soft, rigid, piggy-back and hybrid) have been employed to correct or neutralize the irregular cornea and thereby improve vision. For contact lens intolerant patients or moderate to severe cases of irregular astigmatism that cannot be corrected with corneal contact lenses, scleral lenses offer an alternative. These lenses have been used since the introduction by Fick and Muller in the 1880s.[1,2] The development of gas-permeable (GP) materials and innovations in the design (such as toric and tangential designs), led to a decrease in corneal hypoxia and increased comfort.[3,4] Scleral lenses rest on the bulbar conjunctiva and sclera and vault the cornea; the fluid layer between the lens and cornea both neutralizes the irregular astigmatism and hydrates and protects the corneal surface. Therefore, scleral lenses can be used to provide mechanical protection, relief of symptoms as in dry eyes or to facilitate corneal healing. The main application of scleral lens use is optical correction of the irregular surface, with corneal ectasia being the primary cause.[5–7]

It is well known that corneal curvature can be influenced by corneal contact lenses due to mechanical corneal rubbing or hypoxia.[8–15] Reports on temporary keratometry changes induced by soft or RGP contact lens wear show variable results; both steepening and flattening of normal corneas have been reported. The timing of corneal recovery after discontinuation of corneal contact lenses is variable per contact lens type. Duration of corneal contact lens wear seems proportional to the required time for topography stabilization.[16]

Corneal curvature changes following (short term) miniscleral lens wear have been reported recently in healthy subjects, but at this moment, we are not certain of the corneal effects of full scleral lenses in patients with keratoconus.[17] The fact that there is no mechanical contact between a scleral lens and the cornea could lead to the assumption that corneal curvature is not influenced by this lens type. Changes in both corneal topography and corneal thickness can occur during scleral lens wear. Topographic changes might be induced by fluid pressure behind the scleral lens or by corneal swelling due to hypoxia following scleral lens wear. Besides hypoxia-induced corneal swelling, another hypothesis for increased pachymetry during scleral lens wear is the absence of lid wiper contact and chafing of the surface epithelium during blinking.[18]

Keratoconus patients are often highly dependent on their lenses and have suboptimal vision with spectacles. Therefore, they are often reluctant to remove their lenses for

topography measurements which aim to monitor the keratoconus progression. In cases of progressive keratoconus, corneal crosslinking (CXL) can be performed in order to stabilize the cornea.[19–21] However, since one of the most important inclusion criteria for CXL includes a recent documented topographic progression,[20] accurate topography readings are essential in these patients. In most studies, patients who wear corneal contact lenses are requested to discontinue their lens wear for a certain period of time prior to topography measurements, in order to avoid bias in corneal curvature determination. For scleral lenses, there is no defined consensus on this topic.

In this study, we investigated the influence of full scleral lenses on corneal curvature and pachymetry in patients with keratoconus. A confirmation of the hypothesis that scleral lenses do not manipulate corneal curvature would be valuable for keratoconus patients and would implicate that scleral lens discontinuation could be avoided prior to examinations.

Methods

All keratoconus patients who visited our outpatient clinic at the University Medical Center Utrecht (UMCU) were asked to discontinue their full scleral lenses (size 18-22 mm) at least 1 week before baseline Scheimpflug imaging. For this study, patients were requested to discontinue their scleral lens wear right before CXL treatment, in order to repeat Scheimpflug imaging directly after scleral lens removal.

Inclusion criteria were: keratoconus, scleral lens wear for at least 3 months and discontinuation of scleral lens wear at least 1 week before Scheimpflug imaging. Excluded were patients who wore an inadequately fitted scleral lens and patients with unreliable Scheimpflug images. Scleral lens parameters and fitting were assessed at Visser Contact Lens Practice (n=18) or requested for and supplied by an external contact lens institution (n=2). A standard classification method was used to grade the scleral lens fitting characteristics[6], which was revised after new insights (Table 1): corneal clearance, limbal clearance, scleral fit, lens movement and general lens fitting. Grade 0 was considered ‘optimal’, grade 1 ‘acceptable’ and grade 2 ‘unacceptable’. All scleral lenses consisted of one of the following materials: Boston Equalens II (Oprifocon A, Dk 85 [Polarographic ISO/Fatt method]), Boston XO2 (Hexafocon B, Dk 161 [non-edge corrected ISO/Fatt method]), Boston XO (Hexafocon A, Dk 100 [Polarographic ISO/Fatt method]) which were manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA, USA.

Table 1. Scleral lens fitting classification by Visser et al.

Characteristic	Grade -2 unacceptable	Grade -1 acceptable	Grade 0 optimal	Grade +1 acceptable	Grade +2 unacceptable
Central corneal clearance	Corneal contact	≤0.1 mm	0.1-0.3 mm	>0.3 mm to ≤0.5 mm	>0.5 mm
Limbal corneal clearance	Circumcorneal limbal contact	Circumcorneal <0.05 mm	0.05- 0.2 mm	Circumcorneal >0.2 mm to ≤0.3 mm	Circumcorneal >0.3 mm
Scleral (haptic) fit	Circumcorneal blanching	Segmented/slight blanching	Scleral alignment	Slightly increased edge clearance	Increased edge clearance, with possible trapped air bubbles
Lens movement (push-up test)	Lens suction	Reduced	Gentle	Increased	Excessive
General lens fit			Optimal	Acceptable	Unacceptable

Data were collected after approval of the Medical Ethics Committee of the UMCU. Written informed consent was conducted in accordance to UMCU guidelines.
All measurements were acquired from a rotating Scheimpflug device (Pentacam HR, Oculus Wetzlar, Germany) and performed by the one and the same optometrist. Quality of the measurement was checked, and one high quality examination (valid data >85%) per eye was used for analysis.

Statistics

A sample of at least 18 eyes was required to detect a difference of 1.0 D between the mean K_{max} at two time points and to achieve a power of 0.8 with a significance level of 0.05. Normal distribution of the data was confirmed by the Shapiro-Wilk test of normality. Generalized estimating equations with statistical correction to test for correlations between paired eyes were used to analyze the differences between variables at two time points. A P-value <0.05 was considered statistically significant.

Results

In this study, 24 eyes of 17 patients were enrolled, 10 were female, 7 were male. Mean age was 30 years (range 19-49). Pentacam imaging was performed directly after scleral lens removal and ≥1 week after scleral lens removal.
After exclusions (1 patient showed an improperly fitted scleral lens with a corneal touch in both eyes, in 1 patient the Scheimpflug images were unreliable and of 1 patient the external scleral lens fitting characteristics could not be obtained), 20 eyes of 14 patients were analysed. Of these 20 patients, 6 patients (11 eyes) discontinued scleral lenses for 2 weeks and in 8 patients (9 eyes) lenses were discontinued for 1 week. In 16 out of 20 eyes, both measurements were assessed at a consistent time of day, with a mean difference of 49 minutes (range 11-129). The mean difference in time of day in the other 4 eyes was 293 minutes (range 194-342 minutes).
Directly after scleral lens removal, all 3 curvature parameters were significantly flatter compared to measurements when scleral lenses were removed for ≥1 week, results are listed in Table 2. Average K_{steep} was 0.7 diopters (D) lower (P<0.001), average K_{flat} was 0.5 D lower (P=0.037) and average K_{max} was 1.1 D lower (P<0.001). Directly after scleral lens removal, average optical pachymetry was ±2.5% higher (P<0.001) than ≥1 week after scleral lens removal.

Table 2. Mean keratometry and pachymetry before and after scleral lens removal (n=20).

Time point	K_{steep} diopter	K_{flat} diopter	K_{max} diopter	CCT pupil µm
Directly after scleral lens removal	51.9 ± 5.0	47.5 ± 4.3	57.0 ± 6.7	488 ± 47
≥1 week after scleral lens removal	52.6 ± 5.2	48.0 ± 4.7	58.1 ± 6.8	475 ± 44
P value[a]	<0.001*	0.037*	<0.001*	<0.001*
95% CI diff	-1.2 to -0.3	-0.9 to 0.0	-1.6 to -0.6	8 to 19

K_{steep} = steepest central keratometry value; K_{flat} = flattest central keratometry value; K_{max} = maximal keratometry value; CCT = corneal thickness (pachymetry); 95% CI diff = 95% confidence interval of the difference.
[a] Generalized estimating equations analysis with correction for paired eyes; total number of paired eyes in the analysis is 6.
* Statistically significant.

Table 3 shows the scleral lens fitting results. All components were graded as optimal or acceptable (grade 0 or 1).

Table 3. Scleral lens fitting (n=20).

Grade	-2	-1	0	1	2
Central corneal clearance	0	2	12	6	0
Limbal corneal clearance[a]	0	0	16	3	0
Scleral (haptic) fit	0	0	16	4	0
Movement	0	0	18	2	0
General lens fit	0	0	15	5	0

Grade -2 or 2 = unacceptable; grade -1 or 1 = acceptable; grade 0 = optimal.
[a] In one patient, limbal corneal clearance was not graded.

Discussion

To the best of our knowledge, this is the first report to show the influence of full scleral lenses on corneal curvature and pachymetry in patients with keratoconus. In this study, we found a difference in curvature and pachymetry directly after scleral lens removal compared to ≥1 week of scleral lens removal.

The sample size of this relevant and clinically oriented study was small, no control group was available and measurements at only two time points were assessed. Additional information on scleral lens influence at more than two time points (for instance at 1, 2 and 3 days after lens discontinuation) may have provided more information on the duration of curvature and pachymetry changes induced by scleral lens wear. This was desirable, yet difficult to implement in daily practice.

Our topography and pachymetry measurements were performed by Scheimpflug (Pentacam) imaging, which is considered to be a highly reliable device to measure keratometry and pachymetry in keratoconic corneas.[22,23] The repeatability of measurements with the Pentacam is high and in a study by Koller et al.[24] the standard deviation of repeated K_{max} ranged from 0.017 to 0.039 mm with a mean of 0.024 mm, which corresponds to a mean of approximately 0.1 D.

In a report of 1982 by Kiely et al.[25] in 21 healthy subjects without lens wear, it was shown that pachymetry changes during the day were correlated with keratometry: increased pachymetry after awakening was associated with central corneal flattening. This is in line with the outcome in our keratoconus group: compared to >1 week of scleral lens removal, K_{steep}, K_{flat} and K_{max} were slightly but significantly lower directly after scleral lens removal, in addition to significant corneal swelling. Similar results were shown in a recent report on corneal changes during 3 hours of mini-scleral lens wear in healthy subjects. However, there was no association between pachymetry change and the anterior corneal curvature change, following lens wear. In their study, the timing of the measurement sessions was matched to allow for confounding influence of diurnal variation. In our study, in 4 eyes there was a disparity in time of measurement, which was not accounted for.[17]

Corneal swelling is the principal objective method to determine hypoxia.[26] Physiologic overnight swelling (without lens wear) is approximately 4.5 to 5.5%, shows recovery during the first waking hours and then varies throughout the day.[27,28] Although the small sample size in our study limited the ability to make definite data interpretations, the significant ±2.5% increase in pachymetry directly after scleral lens removal in keratoconic corneas was in line with studies in healthy eyes. Pachymetry changes after scleral lens wear have been reported by Mountfort et al.[29], showing an increase in pachymetry by 0.98 µm per hour with scleral lenses of highly GP material fitted on eight healthy subjects. Pullum and Stapleton[30] described a less than 3% corneal swelling in four healthy subjects with scleral lenses. Depending on the thickness of the fluid layer between lens and cornea, a corneal swelling of 1.5 to 4% in eight healthy subjects was reported recently by Compañ et al.[32] When comparing scleral lens Dk, it seems that Pullum and Stapleton used lower scleral lens Dk's, and the group of Compañ et al. used comparable Dk's compared to our study. The limited temporary increase in pachymetry in our study group was not expected to cause adverse physiological corneal responses; however, individual hypoxia responses may differ. In general, it is recommended to restrict hypoxia-induced swelling by application of highest Dk available materials and minimizing both lens thickness and the fluid layer between lens and cornea.[31,32] The thickness of the fluid layer between lens and cornea was not investigated in this study.

Another explanation for temporary corneal swelling during scleral lens wear could be the elimination of the eyelid influence on epithelial thickness. The thickness of the epithelium is suggested to decrease by 'wiping' of the eyelid on the apex of keratoconus.[18] This effect of corneal thinning by chafing of epithelium during blinking is diminished by vaulting of the scleral lens over the cornea, which allows the corneal epithelium to regain its thickness.

Temporary corneal changes induced by scleral lens wear are of great importance for the clinician when evaluating patients for possible keratoconus progression and assessment of a CXL indication. Corneal changes caused by scleral lens wear, including corneal flattening and swelling, can lead to an underestimation of the level of keratoconus and missing progressive cases.

In conclusion, although there is no mechanical contact between a scleral lens and the cornea, small but statistically significant changes in corneal curvature and thickness were noted 1 to 2 weeks after discontinuation of full scleral lens wear in patients with keratoconus. These changes suggest that accurate assessment of topographic keratoconus progression in patients who wear scleral lenses require the discontinuation of lens wear for some period of time prior to evaluation. The exact duration of the time necessary to allow for reversal of scleral lens-induced corneal changes is unknown, and warrants further study.

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Chapter 9

Summary and conclusions

Closing remarks and future perspectives

Summary

In this thesis the current status and performance of scleral lenses, including two new advances in scleral lens technologies (back-surface toric and tangential scleral lenses) are investigated. Moreover, effective lens-selection criteria, indications for scleral lenses, the effect of scleral lenses on corneal parameters, and the performance of scleral lenses following corneal crosslinking (CXL) were investigated, with the aim of optimizing patient care and comfort.

Chapter 1 gives a general introduction and presents the current state-of-the-art with respect to the fundamental properties, complications, corneal effects, and indications of modern scleral lenses.

Scleral lenses are large-diameter, rigid gas-permeable contact lenses specifically designed to vault the entire corneal and limbal surface, thereby resting on the anterior sclera (conjunctival layer). When a scleral lens is worn, a fluid reservoir is maintained between the anterior cornea and the posterior lens surface. The rigid nature of the lens material—together with the fluid reservoir between the scleral lens and the cornea (also referred to as the clearance)—can neutralize anterior corneal irregularities and can both hydrate and protect the corneal surface. Unlike corneal lenses, scleral lenses do not have mechanical contact with the cornea, thereby minimizing corneal stress; moreover, fitting of a scleral lens does not depend upon corneal shape. These unique functional properties of scleral lenses make them well-suited to correcting vision problems caused by keratoconus and other corneal irregularities. Scleral lenses also provide corneal protection in patients with various forms of ocular surface diseases who are otherwise unable to tolerate wearing contact lenses.

The exact prevalence of scleral lens-associated complications is not known, although severe complications such as microbial keratitis are only incidentally reported. However, any potential effects of scleral lens wear on ocular physiology, including hypoxia and changes in physiological parameters, should be minimized by using the highest Dk materials available and by reducing both the thickness of the scleral lens and the clearance between the lens and the cornea. In addition, other complications have been reported with scleral lenses; these complications can reduce visual clarity during lens wear and include deposits on the lens surface, poor lens surface wettability, and debris in the fluid reservoir (lens fogging). Together with tight lens adherence and conjunctival folding underneath the scleral lens, which can occur in some patients, these appear to be the most challenging

complications associated with scleral lens wear. Scleral lenses also have a relatively long learning curve with respect to lens fitting and handling, and their large size can cause psychological resistance among patients and/or differences in the aperture between the left and right eyes when only one lens is worn.

Scleral lenses are classified into mini-scleral lenses and large-scleral lenses, they are ≤6 mm and >6 mm, respectively, larger than the horizontal visual iris diameter (HVID). Large-scleral lenses have the largest pre-corneal fluid reservoir capacity and the largest bearing area on the anterior sclera, thus providing maximum protection of the anterior eye and maximally balanced bearing area. However, mini-scleral lens designs are indicated for decreasing the effect on the aperture between the eyelids and with local scleral shape irregularities, as these lenses interfere less with the shape of the peripheral sclera. This thesis primarily concerns large-scleral lenses, as well-fitting mini-scleral lenses have only recently become available in our arsenal.

Thanks to improved lens availability and better performance due to new advances in lens materials (e.g., materials with higher Dk values), design (e.g., nonrotationally symmetrical and tangential designs), and manufacturing, scleral lenses have drawn increasing interest in recent years.

Chapter 2 introduces a novel lens-selection algorithm that was designed for the two principal uses of medical contact lenses: to correct irregular astigmatism and to bandage the corneal surface. This algorithm selects a specific contact lens type based on the severity of the disorder and on the presence of additional indications and/or complicating factors. In addition, this chapter summarizes a practical approach for specifically selecting the appropriate type of soft lenses (including conventional soft lenses or silicone hydrogel lenses). The objective and subjective performance of medical contact lenses that were fitted for a broad variety of clinical indications using the lens selection algorithm were prospectively studied in 281 eyes in 281 patients. The most common diagnoses were keratoconus (in 25% of eyes), dry eye disease (23%), and keratoplasty (20%); the most common types of contact lenses were scleral lenses (in 53% of eyes) and either silicone hydrogel lenses or conventional soft lenses (35%). High outcome was achieved in terms of best-corrected visual acuity (median increase of 0.15 logMAR with contact lenses) and overall patient satisfaction (81% of patients reported an overall satisfaction score ≥70). Importantly, when using the algorithm, similar outcomes were achieved with respect to both soft lenses and scleral lenses. These results highlight the important role of scleral lenses in the context of other contact lens types, and they emphasize the need for practitioners to

be generally familiar with a wide range of lens types and the process of selecting lenses tailored to the individual patient's needs.

Chapter 3 discusses the advanced back-surface toric scleral lens design, which was developed by our team. The purpose of this new nonrotationally symmetrical lens design is to distribute lens pressure more evenly over the sclera and to improve the lens' fit on toric-shaped scleral surfaces. Specifically, this chapter examines the positional stability of back-surface toric scleral lenses on 43 eyes (in 43 patients); to measure positional stability, the lens was rotated in the nasal and temporal direction by 60 degrees, and the time interval to return to the original position was measured. In addition, the comfort (ranging from 0 [very poor] to 10 [very good]) and wearing time of these toric scleral lenses were compared to back-surface spherical scleral lenses (n=27 eyes). Consistent stabilization of the back-surface toric scleral lenses was reflected in the rapid rate in which all of the lenses returned to the original position (with median intervals of 4 and 6 seconds after nasal and temporal rotation, respectively). Remarkably, symmetrical stabilization of the flattest meridian of the back-surface of the scleral lens was demonstrated by a median axis of stabilization of 137 degrees and 47 degrees in the right and left eyes, respectively. High patient satisfaction was reported, with a median comfort score of 8 (out of 10) and a median daily wearing time of 16 hours. Patient interviews revealed that both comfort and wearing time increased significantly (by one point and two hours, respectively) after changing from back-surface spherical scleral lenses to lenses with a back-surface toric design. Moreover, the finding that back-surface toric scleral lenses have high positional stability means that the lens can contain a front-surface cylinder, which can greatly improve vision in patients with residual astigmatism.

Chapter 4 summarizes the indications and clinical performance of modern scleral lenses in 284 eyes of 178 patients. At the time of the study, back-surface toric scleral lenses had been introduced only recently, and this lens design comprised approximately half of all fitted scleral lens designs. In total, the following four scleral lens types were included: two back-surface spherical (spherical [45% of the lenses] and front-surface toric [2% of the lenses]) designs and two back-surface toric (back-surface toric [25% of the lenses] and bitoric [28% of the lenses]) designs. In this cross-sectional survey, visual acuity and slit lamp findings were recorded; moreover, a specifically designed classification for scleral lens fitting was introduced in order to evaluate clinical performance. The diagnoses were keratoconus (in 50% of eyes), keratoplasty (20%), other forms of irregular astigmatism (13%), dry eye

disease (5%), corneal dystrophy (4%), and multiple diagnoses (8%). Clinical examinations revealed that scleral lenses provided a sharp increase in visual acuity (median increase, 0.45 [Snellen decimal]) and had a safe physiological response in the anterior eye. The majority of scleral lenses had optimal fitting characteristics, and all patients were able to continue wearing scleral lenses (with the same lens parameters in 79% of cases). A notable finding was that a refit of the scleral lens was needed in 31% of patients with a back-surface spherical design, which was considerably higher than the patients with back-surface toric designs (12%).

Chapter 5 discusses the subjective performance of scleral lenses measured in the 178 patients (284 eyes) in the cross-sectional survey presented in Chapter 4. An interview (using a five-point Likert scale) and a questionnaire (using a 100-mm visual analog scale [VAS]) were used to quantify patient satisfaction. In addition, the interview results were used to compare patient satisfaction with the former type of correction, which included rigid gas-permeable (RGP) corneal contact lenses (50%), glasses (19%), other types of contact lenses (19%), and no correction at all (11%). The current scleral lenses had been worn for a median of 16 hours per day and were worn throughout the day (i.e., without interruption) by 51% of the patients. Patients with dry eye disease had a trend towards less favorable results; these patients reported a median wearing time of 14 hours per day, and 77% of patients with dry eye disease took one or more breaks from wearing their lenses during the day. The scleral lenses being currently worn scored high based on the interview scores (median score, 4) and questionnaire (median score, ≥75). Importantly, significant increases in scores were reported with the current scleral lens design compared to the former type of correction: specifically, scores regarding comfort, visual quality, and overall satisfaction were higher in 79%, 78%, and 88% of patients, respectively (P<0.001). Furthermore, the interview results revealed that comfort, visual quality, and overall satisfaction were higher in 62%, 37%, and 66% of patients, respectively, in 99 patients who changed from wearing back-surface spherical scleral lenses to wearing back-surface toric scleral lenses.

Chapter 6 evaluates a newly introduced scleral lens design that has a bitangential (nonrotationally symmetrical) periphery; this lens design was developed in order to fit more properly on eyes that have a tangentially shaped anterior sclera. In this prospective study, subjective performance (by means of an interview with a five-point scale), visual acuity, and scleral lens-fitting characteristics were measured in 213 eyes (in 144 patients). Patients with keratoconus (57%), ocular surface disease (15%), penetrating keratoplasty (14%), another form of irregular astigmatism (13%), or other diagnoses (1%) were fitted for scleral lenses.

The results revealed that tangential scleral lenses had excellent objective performance; specifically, the median best-corrected visual acuity with the scleral lenses was 0.8 (Snellen decimal), and good fitting characteristics were observed (97.7% of patients had optimum values with respect to lens movement and position). Furthermore, these lenses were satisfactory to patients, which yielding a comfort score >4 (out of 5) in 77% of eyes. The high oxygen-permeable material Menicon Z (Tisilfocon A, Menicon Co. Ltd., Nagoya, Japan) was available for 10 (5%) of the eyes. This material was introduced to provide an added benefit to corneas with high oxygen demand; however, their precise benefit must be investigated further. Notably, as discussed in Chapter 3, symmetric stabilization of the flattest meridian was reflected by comparable median axes of stabilisation (140 degrees and 60 degrees in the right and left eyes, respectively).

Chapter 7 evaluates the tolerance and fitting aspects of scleral lenses before and one year after corneal crosslinking (CXL). This prospective study evaluated 18 eyes (in 18 patients) that underwent CXL for progressive keratoconus and had been wearing well-fitting scleral lenses before CXL. In principle—and unlike corneal lens wear—scleral lens wear should not be affected by changes in corneal curvature following CXL, as scleral lenses do not mechanically touch the cornea. This hypothesis was supported by the finding of stable subjective tolerance of scleral lenses in patients following CXL; specifically, similar daily wearing times (median, 16 hours per day) and similar high VAS scores for overall satisfaction were measured (81 of 100 mm) one year after CXL. Moreover, no significant change was measured with respect to scleral lens-corrected distance visual acuity. Furthermore, 11 of the 18 eyes (61%) required a change in the fit and/or power of the scleral lens; however, whether these changes could be attributed solely to CXL is unknown, as clinical changes occur over time regardless of CXL and could account for at least some of these changes.

Chapter 8 examines the effect of scleral lens wear on corneal keratometry and/or pachymetry values in patients with keratoconus. In this intervention study, these measurements were performed at two time points: directly after scleral lens removal and ≥1 week (range 1 to 2 weeks) after scleral lens removal. Although scleral lenses do not mechanically contact the cornea, directly after removing the scleral lens, corneal thickness increased by 2.7%, and the cornea flattened by 0.7 diopter (D) (K_{steep}), 0.5 D (K_{flat}), and 1.1 D (K_{max}). These changes suggest that in order to accurately assess the progression of keratoconus using topography in patients who wear scleral lenses, lens wear should be discontinued for a certain period of time prior to assessment, as these changes can cause an underestimation

of disease progression. However, the precise minimum time interval between removing the scleral lens and the complete reversal of scleral lens-induced corneal changes is not currently known.

Closing remarks and future perspectives

In this thesis the objective and subjective performance of scleral lenses are investigated and the benefits provided by the advances in scleral lens technologies are assessed. Understanding better the value and indications of scleral lenses will ultimately optimize patient care both in terms of accessibility to these scleral lens designs and in terms of patient expectations. Importantly, the improved performance of scleral lenses due to recent advances in lens design, together with increased knowledge regarding desired fitting characteristics, have led to improved patient comfort.

When fitting patients with medical lenses, eye care practitioners must recognize the value of scleral lenses in the context of other contact lens types. Several studies evaluated the fitting of medical contact lenses[1-6] or scleral lenses[7,8] in a variety of settings; however, these studies were largely one-sided, as they generally evaluated a single type of contact lens or a single indication. The lens-selection algorithm is based on peer-reviewed literature and was developed by our team, which has many years of experience and research regarding contact lenses. This algorithm provides an overarching method for selecting the optimal contact lens for a wide variety of indications, and contact lenses that were fitted using this algorithm yielded satisfactory results in patients. Thus, the value of scleral lenses in the context of other contact lenses is clear, and our lens-selection algorithm can enable practitioners to achieve the desired results. This study has some considerations with respect to the patient population, which was derived from a tertiary academic center, which generally sees patients with relatively severe clinical diagnoses and/or advanced stages of disease. This selection bias may have resulted in a disproportionate selection of more advanced contact lens indications. Future prospective studies that represent the more general population will likely reveal important information regarding a wide range of contact lens types in patients in earlier stages of disease.

The indications for scleral lenses identified in this thesis are largely consistent with other studies that included various diagnoses[9-14], showing a predominance of corneal irregularities. However, the value of using scleral lenses to manage ocular surface disease is becoming increasingly known and reported.[15] The significantly improved comfort and

visual improvement associated with scleral lenses is particularly relevant to these patients, many of whom have few other options.

In this thesis, the inclusion criterion of patients who wore scleral lenses for ≥3 months may represent a limitation in terms of determining the overall success rate of scleral lenses in all patients referred to our team. Future studies that enroll patients directly at the start of the fitting process should help overcome this limitation. However, the specific inclusion of patients who have adapted to wearing scleral lenses (≥3 months) allowed us to avoid any potential bias caused by the adaptation period (in which several lens parameters, including lens power, may need to be revised). Another limitation is related to the cross-sectional design of our studies, which did not allow us to determine the precise incidence of complications. In their recent reviews of scleral lenses, van der Worp et al.[7] and Schornack[8] concluded that adverse events are rarely reported in these modalities; nevertheless, future research is needed in order to determine the prevalence of complications.

The introduced back-surface toric scleral lenses have improved objective and subjective performance and excellent positional stability on the eye. This advance has accelerated ongoing developments in scleral lens design—including the application of aberration correction—and has sparked an interest in scleral lenses and anterior scleral shape. In our clinical experience, a paradigm shift has occurred from fitting back-surface spherical scleral lenses towards fitting back-surface toric designs; thus, spherical designs are fitted only incidentally in current practice. Studies regarding corneal shape support our clinical experience by demonstrating that the shape of the anterior sclera is often asymmetrical;[16,17] in addition, the shape of the anterior sclera is often tangential rather than curved,[16,18] which has led to the idea of using tangentially shaped scleral lenses rather than curved scleral lenses. The performance of tangential designs was found to be effective based on our evaluation of the performance of these scleral lenses in patients within the first year of fitting. Nevertheless, the performance of curved and tangential lens designs must be compared directly in order to detect any differences between these two designs. However, because anterior scleral shape is unique in each patient, whether a tangential or curved design is warranted must be determined for each individual patient. Therefore, clinicians should ideally have access to topographic devices that can accurately measure the scleral profile in order to select between a tangential or curved scleral lens design in each patient.

In this thesis, two studies focused on scleral lens wear in relation to corneal crosslinking (CXL), as an increasing percentage of scleral lens wearers receive screening and/or CXL treatment. CXL is a minimally invasive procedure that can help stabilize the cornea in progressive keratoconus. One of the most important selection criteria for CXL

is recently documented topographic progression,[19] which requires reliable topography measurements. Prior to this thesis, the effects of scleral lenses on corneal topography in eyes with keratoconus had not been investigated. The flattening of the corneal curvature and the increased corneal thickness that we observed immediately after removing the lens are highly relevant, as measurements obtained early after removing the scleral lens can underestimate the progression of keratoconus and/or overestimate the effect of CXL. This finding indicates the need to temporarily discontinue scleral lens wear prior to performing topography measurements. Unfortunately, the published literature does not appear to agree with respect to the minimum duration of discontinuing scleral lens wear prior to measuring corneal topography, nor does it agree with respect to the duration of scleral lens wear following CXL treatment.[20] In our study, patients were advised to discontinue scleral lens wear for at least one week prior to topography measurements and one month after undergoing CXL. Future studies designed to determine the minimum discontinuation time would be highly beneficial to keratoconus patients, given that discontinuing scleral lens wear—even for a short period of time—can have direct effects on their daily function because they are highly dependent upon their lenses and can achieve only suboptimal vision with spectacles.

Our finding of stable scleral lens tolerance among scleral lens wearers following CXL can help educate patients with respect to their expectations regarding scleral lens wear following this procedure. Moreover, our findings underscore the importance of re-evaluating the scleral lens fit in post-CXL patients, particularly given that scleral lens fitting parameters may have changed after the procedure. This prospective research should be expanded to include other types of contact lenses because this may reveal valuable information with respect to patients with keratoconus, particularly in the case of corneal contact lenses, as their fitting and tolerance can be influenced by the decreased corneal sensitivity[21] and corneal flattening[22,23] that occurs following CXL.

Eventually, two additional technological advances were developed and have been added to our arsenal. These two advances are the highly oxygen-permeable material Menicon Z (Menicon Co. Ltd., Nagoya, Japan) and the innovative mini-scleral lens design. The precise clinical value and performance of these developments are currently under investigation.

In summary, the studies performed in this thesis were designed to improve patient comfort by optimizing lens-selection efficiency, scleral lens tolerance, scleral lens fitting characteristics, and best scleral lens-corrected visual acuity. An addition goal was to educate patients with respect to their expectations regarding scleral lenses. Despite

the extensive research included in this thesis, much remains to be explored in this field, including studying the metabolic and mechanical effects of these lenses on the anterior eye and tear film (particularly the origin and management of debris in the fluid reservoir), as well as the precise prevalence of complications and associated risk factors. Future technological innovations must be further developed, including the incorporation of higher-order aberration correction. Finally, advances in scleral shape topography with respect to fitting and designing scleral lenses will likely improve scleral lens fitting and patient comfort even further.

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Chapter 10

Samenvatting en conclusies

Samenvatting

In dit proefschrift worden de huidige toepassing en performance van scleralenzen, inclusief twee geavanceerde innovaties (binnentorische en tangentiële scleralenzen), onderzocht. Daarnaast worden de criteria voor effectieve lensselectie, indicaties voor scleralenzen, het effect van scleralenzen op corneale parameters en de performance van scleralenzen na 'corneal crosslinking' (CXL) onderzocht, met als doel optimalisering van zorg en comfort voor de patiënt.

Hoofdstuk 1 geeft een algemene inleiding en presenteert de fundamentele eigenschappen van en de complicaties bij scleralenzen, alsmede de klinische indicaties voor deze lenzen. Scleralenzen zijn vormstabiele zuurstofdoorlatende contactlenzen met een grote diameter die het gehele corneale en limbale oppervlak overkoepelen, waarbij ze steunen op de anterieure sclera (de conjunctiva). Tijdens het dragen van een scleralens wordt tussen de anterieure cornea en het posteriore lensoppervlak een vochtreservoir gecreëerd (ook wel de 'clearance' genoemd). De rigiditeit van het lensmateriaal kan, samen met het vochtreservoir tussen de scleralens en de cornea, anterieure cornea-irregulariteiten neutraliseren en het corneaoppervlak zowel hydrateren als beschermen. In tegenstelling tot corneale lenzen maken scleralenzen geen mechanisch contact met de cornea, hetgeen de belasting van de cornea minimaliseert. Bovendien is de passing van een scleralens niet afhankelijk van de corneatopografie. Door deze unieke functionele eigenschappen van scleralenzen zijn ze onder andere zeer geschikt voor de correctie van visusproblemen die worden veroorzaakt door keratoconus en andere cornea-irregulariteiten. Tevens geven scleralenzen bescherming van de cornea bij patiënten met aandoeningen waarbij het oppervlak van het oog is aangedaan (de zogenaamde ocular surface diseases) die anders geen contactlenzen zouden kunnen dragen.
De exacte prevalentie van complicaties bij het dragen van scleralenzen is niet systematisch onderzocht, maar ernstige complicaties als microbiële keratitis zijn slechts incidenteel gerapporteerd. Eventuele potentiële effecten van het dragen van scleralenzen op de oculaire fysiologie, zoals hypoxie en veranderingen in de fysiologische parameters, moeten zo veel mogelijk worden beperkt door de toepassing van materialen met de hoogst mogelijke Dk-waarde en door zowel de dikte van de scleralens alsmede de 'clearance' tussen lens en cornea zo minimaal mogelijk te houden. Daarnaast zijn er complicaties bekend die de visuele helderheid tijdens het dragen van scleralenzen kunnen verminderen; deze betreffen onder meer aanslag op het lensoppervlak, slechte oppervlaktebevochtiging

van de lens en débris in het vochtreservoir (het troebel worden van de vochtlaag). Overige complicaties die soms voorkomen tijdens het dragen van scleralenzen zijn lensadhesie en conjunctivale plooivorming onder de scleralens. Verder hebben de aanmeting en het hanteren van scleralenzen een relatief lange leercurve, en de grote afmeting van de lens kan bij sommige patiënten psychische weerstand oproepen, en kan soms leiden tot verschillen in de grootte van de lidspleetopening tussen het linker- en rechter oog wanneer er maar één lens wordt gedragen.
Scleralenzen kunnen worden ingedeeld in mini-scleralenzen en 'full'-scleralenzen; deze zijn respectievelijk ≤6 mm en >6 mm groter dan de horizontale zichtbare irisdiameter (HVID). 'Full'-scleralenzen hebben de grootste capaciteit wat betreft het precorneale vloeistofreservoir en het grootste contactoppervlak op de anterieure sclera, resulterend in maximale bescherming van het voorste oogsegment en een maximaal uitgebalanceerd contactoppervlak. Mini-scleralenzen zijn echter geïndiceerd als er verminderd effect op de lidspleetopening tussen de oogleden is gewenst en bij lokale verhevenheden van de sclera, aangezien deze lenzen minder interfereren met de vorm van de perifere sclera. In dit proefschrift worden voornamelijk 'full'-scleralenzen beschreven, aangezien we pas recent beschikking hebben over mini-scleralenzen met een goede pasvorm.
Dankzij de toegenomen beschikbaarheid van scleralenzen en een betere performance van deze lenzen door nieuwe ontwikkelingen op het gebied van lensmaterialen (bijv. materialen met hogere Dk-waarden), ontwerp (bijv. niet-rotatiesymmetrische en tangentiële ontwerpen) en fabricage, is de belangstelling voor scleralenzen in de afgelopen jaren toegenomen.

In **Hoofdstuk 2** wordt een nieuw algoritme voor lensselectie geïntroduceerd, welke werd ontwikkeld voor de twee belangrijkste toepassingen van medische contactlenzen, namelijk de correctie van irregulair astigmatisme en bandage van het corneaoppervlak. Dit algoritme selecteert een specifiek type contactlens op basis van de ernst van de aandoening en op de aanwezigheid van bijkomende indicaties en/of complicerende factoren. Dit hoofdstuk geeft daarnaast een richtlijn voor het selecteren van het juiste type zachte lens (zowel conventionele zachte lenzen als siliconen hydrogel-lenzen). De objectieve en subjectieve performance van medische contactlenzen die met behulp van het algoritme werden aangemeten, werden prospectief onderzocht bij 281 ogen van 281 patiënten. De meest voorkomende diagnoses waren keratoconus (bij 25% van de ogen), droge ogen syndroom (23%) en keratoplastiek (20%); de meest gebruikte typen contactlenzen waren scleralenzen (bij 53% van de ogen) en siliconen hydrogel-lenzen of conventionele zachte lenzen (35%). Een hoge uitkomst werd bereikt voor de best gecorrigeerde visus

(mediane toename van 0.15 logMAR met contactlenzen) en algehele patiënttevredenheid (bij 81% van de patiënten was de algehele tevredenheidsscore ≥70). Bij de toepassing van het algoritme werden vergelijkbare uitkomsten verkregen voor zowel zachte lenzen als scleralenzen. Deze resultaten markeren de belangrijke rol van scleralenzen binnen de context van andere typen contactlenzen, en tevens de noodzaak dat er in de medische contactlenspraktijk voldoende diversiteit aan lenstypen en een procedure van lensselectie die is toegesneden op de individuele behoeften van de patiënt, beschikbaar moeten zijn.

In **Hoofdstuk 3** wordt het geavanceerde binnentorische scleralensontwerp onderzocht, welke door ons team werd geïntroduceerd. Dit niet-rotatiesymmetrische lensontwerp is ontwikkeld voor een gelijkmatigere verdeling van de lensdruk over de sclera en voor een betere passing van de lens op torisch gevormde scleraoppervlakken. Dit hoofdstuk onderzoekt de positionele stabiliteit van binnentorische scleralenzen op 43 ogen (bij 43 patiënten); om deze te meten werd de lens 60 graden in de nasale en temporale richting verdraaid en werd het tijdsinterval gemeten tot de lens weer in zijn oorspronkelijke positie stond. Daarnaast werden het comfort (variërend van 0 [zeer slecht] tot 10 [zeer goed]) en de draagtijd van deze torische scleralenzen vergeleken met scleralenzen met een sferische binnengeometrie (n=27 ogen). De consistente stabilisatie van binnentorische scleralenzen werd aangetoond door de snelheid waarmee alle lenzen terugkeerden naar hun oorspronkelijke positie (met mediane intervallen van 4 en 6 seconden na respectievelijk nasale en temporale draaiing). Een opvallende bevinding was de symmetrische stabilisatie van de vlakste meridiaan, de mediane stabilisatie-asstand was 137 graden bij het rechter oog en 47 graden bij het linker oog. Er werd een hoge patiënttevredenheid gerapporteerd, met een mediane score voor comfort van 8 (uit 10) en een mediane draagtijd van 16 uur per dag. Uit patiëntinterviews kwam naar voren dat zowel comfort als draagtijd aanzienlijk toenamen (met respectievelijk één punt en twee uur) na overstappen van scleralenzen met een sferische binnengeometrie op lenzen met een binnentorisch ontwerp. Daarnaast maakt de goede positionele stabiliteit van de scleralens de correctie met een frontcilinder mogelijk, waardoor bij patiënten met rest-astigmatisme de visus sterk kan verbeteren.

In **Hoofdstuk 4** worden de indicaties en klinische performance van moderne scleralenzen in 284 ogen van 178 patiënten geëvalueerd. Ten tijde van het onderzoek waren binnentorische scleralenzen nog maar recent geïntroduceerd en dit lensontwerp omvatte ongeveer de helft van alle aangemeten scleralenzen. In totaal werden de volgende vier typen scleralenzen in het onderzoek opgenomen: twee typen met een sferische

binnengeometrie (sferisch [45% van de lenzen] en front-torisch [2% van de lenzen]) en twee binnentorische ontwerpen (binnentorisch [25% van de lenzen] en bitorisch [28% van de lenzen]). In dit cross-sectionele onderzoek werden de visus en spleetlampbevindingen onderzocht, daarnaast werd een classificatie voor de kenmerken van de scleralenspassing geïntroduceerd voor beoordeling van de aanpastechnische aspecten. De diagnoses waren keratoconus (bij 50% van de ogen), keratoplastiek (20%), andere vormen van irregulair astigmatisme (13%), droge ogen syndroom (5%), corneadystrofie (4%) en meervoudige diagnoses (8%). De resultaten toonden een forse toename van de visus met scleralens (mediane toename, 0.45 [Snellen-decimaal]) en een veilige fysiologische respons van het voorste oogsegment. De meeste scleralenzen hadden een optimale lenspassing en alle patiënten konden scleralenzen blijven dragen (in 79% van de gevallen met dezelfde lensparameters). Opvallend was dat bij 31% van de patiënten met een sferisch ontwerp heraanmeting van de scleralenzen noodzakelijk was; dit percentage was aanzienlijk hoger dan bij de patiënten met een binnentorisch ontwerp (12%).

Hoofdstuk 5 beschrijft de subjectieve performance van scleralenzen gemeten bij de 178 patiënten (284 ogen) in het cross-sectionele onderzoek gepresenteerd in hoofdstuk 4. Een interview (op basis van een Likertschaal van vijf punten) en een vragenlijst (op basis van een 100-mm visuele analoge schaal [VAS]) werden gebruikt voor kwantificering van de patiënttevredenheid. Daarnaast werd de patiënttevredenheid van de huidige scleralens vergeleken met het vorige type correctiemiddel, dit betrof vormstabiele zuurstofdoorlatende (RGP) corneale contactlenzen (50%), brilcorrectie (19%), andere typen contactlenzen (19%) en helemaal geen correctie (11%). De huidige scleralenzen hadden een mediane draagtijd van 16 uur per dag en werden door 51% van de patiënten zonder onderbreking gedragen. Patiënten met een droge ogen syndroom vertoonden een trend naar minder gunstige resultaten; deze patiënten hadden een mediane draagtijd van 14 uur per dag en 77% van hen nam overdag een of meerdere keren hun lenzen uit. De huidige scleralenzen scoorden hoog bij het interview (mediane score, 4) en de vragenlijst (mediane score, ≥75). Daarbij waren er significante toenames in de scores van de huidige scleralens vergeleken met het vorige correctiemiddel, de scores voor comfort, kwaliteit van het gezichtsvermogen en algehele tevredenheid waren hoger bij respectievelijk 79%, 78%, en 88% van de patiënten (P<0.001). Ook bleek uit de interviewresultaten dat comfort, kwaliteit van het gezichtsvermogen en algehele tevredenheid hoger waren bij respectievelijk 62%, 37% en 66% van de 99 patiënten die van sferische scleralensontwerpen op binnentorische scleralenzen overstapten.

In **Hoofdstuk 6** wordt een scleralensontwerp met een bitangentiële (niet-rotatiesymmetrische) periferie geëvalueerd. Dit lensontwerp werd geïntroduceerd voor een betere passing op ogen met een tangentieel gevormde anterieure sclera. In deze prospectieve studie werden bij 213 ogen (van 144 patiënten) de subjectieve prestaties (met behulp van een vijf punten beoordelingsschaal), visus en passing van de scleralenzen onderzocht. De indicaties bestonden uit keratoconus (57%), ocular surface diseases (15%), penetrerende keratoplastiek (14%), een andere vorm van irregulair astigmatisme (13%) of overige diagnoses (1%). De tangentiële scleralenzen toonden uitstekende objectieve prestaties; de mediaan van de best gecorrigeerde visus met de scleralenzen was 0.8 (Snellen-decimaal) en er werd een goede lenspassing waargenomen (97.7% van de scleralenzen hadden een optimale lensbeweging en -positie). Tevens waren er goede subjectieve resultaten, de score voor comfort was ≥4 (van 5) voor 77% van de ogen. Het hoogzuurstofdoorlatende materiaal Menicon Z (Tisilfocon A, Menicon Co. Ltd., Nagoya, Japan) was voor 10 (5%) van de ogen beschikbaar. Dit materiaal werd geïntroduceerd voor corneae met een hoge zuurstofbehoefte; de exacte waarde van dit materiaal moet echter nog verder worden onderzocht. Opmerkelijk is dat, net zoals in hoofdstuk 3, er een symmetrische stabilisatie van de vlakste meridiaan werd gevonden, namelijk 140 graden en 60 graden in respectievelijk het rechter en het linker oog.

In **Hoofdstuk 7** worden zowel de tolerantie als de scleralenspassing, voorafgaand aan en één jaar na CXL vergeleken. In deze prospectieve studie werden 18 ogen (van 18 patiënten) met goed passende scleralenzen geanalyseerd die een CXL behandeling kregen voor progressieve keratoconus. Het dragen van scleralenzen zou, in tegenstelling tot het dragen van corneale lenzen, niet beïnvloed moeten worden door veranderingen in corneatopografie na CXL, aangezien scleralenzen de cornea niet raken. Deze hypothese werd ondersteund door de stabiele resultaten die werden gevonden één jaar na CXL voor de draagtijden (mediaan, 16 uur per dag), algehele lenstevredenheid (81 op de 100-mm VAS) en de best gecorrigeerde visus met scleralens (1.0 Snellen-decimaal, 0.03 LogMAR). Bij 11 van de 18 ogen (61%) was de passing en/of sterkte van de scleralens gewijzigd; het is echter niet duidelijk of deze veranderingen uitsluitend waren toe te schrijven aan CXL, aangezien veranderingen van pasvorm in de loop van de tijd, ongeacht CXL, kunnen optreden.

In **Hoofdstuk 8** wordt het effect van het dragen van scleralenzen op de keratometrie- en pachymetriewaarden bij 20 ogen van 14 patiënten met keratoconus onderzocht. In deze interventiestudie werden deze metingen op twee tijdpunten uitgevoerd: direct na uitnemen van de scleralens en nadat de lens ≥1 week (range 1 tot 2 weken) niet gedragen was. Hoewel scleralenzen geen mechanisch contact maken met de cornea, was de corneadikte direct na uitnemen van de scleralens met 2.7% toegenomen en was de cornea afgevlakt met 0.7 dioptrie (D) (K_{steep}), 0.5 D (K_{flat}) en 1.1 D (K_{max}). Deze veranderingen duiden erop dat scleralenzen gedurende een bepaalde periode vóór keratometrie- en pachymetriemeting moeten worden uitgenomen, teneinde nauwkeurig eventuele progressie van keratoconus te kunnen vaststellen, aangezien deze veranderingen kunnen leiden tot een onderschatting van de progressie. Het tijdsinterval tussen het uitnemen van de scleralens en het ongedaan maken van de door de scleralens geïnduceerde corneaveranderingen is onduidelijk.

List of abbreviations

ANOVA	analysis of variance
BCR	base curve radius
BCVA	best-corrected visual acuity
CCT	central corneal thickness
CDVA	corrected distance visual acuity
CL	contact lens
CXL	corneal crosslinking
D	diopter
Dk	oxygen permeability, D = oxygen diffusion coefficient, k = oxygen solubility of a contact lens material
EBMD	epithelial basement membrane dystrophy (former alternative name: map-dot-fingerprint dystrophy [MDF])
GP	gas-permeable
HVID	horizontal visual iris diameter
K_{flat}	flattest central keratometry value
K_{max}	maximal keratometry value
K_{steep}	steepest central keratometry value
LASEK	laser-assisted subepithelial keratectomy
LASIK	laser-assisted in situ keratomileusis
logMAR	logarithm of the minimal angle of resolution
OCT	optical coherence tomography
OSD	ocular surface disease
PKP	penetrating keratoplasty
PMD	pellucid marginal degeneration
PMMA	polymethyl methacrylate
PRK	photorefractive keratectomy
RGP	rigid gas-permeable
RK	radial keratotomy
SAS	Statistical Analysis System
SiHy	silicone hydrogel
UMCU	University Medical Center Utrecht
VA	visual acuity
VAS	visual analog scale

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Curriculum vitae

Esther-Simone Benraad-Visser was born on May 28, 1971 in Rosmalen, the Netherlands. After graduation from secondary school in 1988 (HAVO, Notre Dame des Anges, Ubbergen) and 1990 (VWO, Canisius College Mater Dei, Nijmegen), she attended a year of orientation at the Cloese, Maarssen. In 1995, she graduated with a degree in Optometry from the Hogeschool Utrecht in Utrecht, the Netherlands. During her studies, she completed a preregistration program with the Contact Lens Department at Moorfields Eye Hospital in London, UK. After graduation, she went to the US, where she participated in an education/research program at the University of Houston's College of Optometry in Houston, Texas; for her studies in Houston, she received a stipend from the Algemene Nederlandse Vereniging van Contactlensspecialisten (ANVC).

In 1996, she joined the Visser Contactlenzenpraktijk (Visser Contact Lens Practice). In this practice, which was founded by her parents in 1977, she furthered her specialization in fitting scleral lenses by working at several practices, hospitals, and university hospitals in the Netherlands. In 2005, she received her Master of Science degree with distinction at City University in London, UK; her research project was focused on scleral lenses.

From 2002 through 2007, she was a member of the editorial committee at VISUS, a Dutch journal that publishes articles on contact lenses and optometry. In 2010, she was invited to become a fellow at the Scleral Lens Education Society, and since 2014, she has served as a member of the society's Fellowship Committee, reviewing fellowship applications.

In 2005, she became a co-owner (together with her brother) of the Visser Contact-lenzenpraktijk, serving as the technical director. She currently presides as the Chair of the practice's Scleral Lens Fitting and Development team. In addition to her clinical work, she is also an active researcher; she currently works with the Utrecht Cornea Research Group at the Department of Ophthalmology, University Medical Center Utrecht.

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