Update on Scleral Lenses: A Review of Recent Literature

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Disclosures
• Mindy Toabe: Essilor
• Muriel Schornack: Advisory Board, Bausch + Lomb

Objectives
• Define study designs in peer-reviewed literature in the field of scleral lenses
• Review current literature regarding scleral lens prescription and management
• Discuss emerging areas of interest in the field of scleral lenses
• Suggest topics for future study

Introduction

Overview of Literature
• Case reports/case series
• Retrospective reviews
• Prospective observational studies
• Reviews of systemic/ocular disease
• Reports (theoretical/clinical) of scleral lens effects on anterior segment structures
• Miscellaneous reports

A Review of Recent Literature

Fitting the Scleral Contact Lens

Retrospective 4%
Prospective 19%
Review of Ocular and Systemic Disease 23%
Observations/Case Series of Scleral Surface Wound 15%
Other 10%
Case Reports/Cases 9%

### Pellicid Marginal Degeneration

**Prospective**

Anna, L., Allmers, D. Clinical outcomes of scleral Minis lenses for visual rehabilitation in patients with pellicid marginal degeneration

- VA improved from 0.42±0.15 Snellen to 0.75±0.15 with mean gain of 3.3 lines
- 3 patients developed hydrops within the first 3 months

**Retrospective**

Rathi, V., Dumpati, S., et al. Scleral contact lenses in the management of pellicid marginal degeneration

- Visual acuity improved log MAR 0.45±0.31 to 0.05±0.08
- 3 patients developed hydrops within the first 3 months

### Penetrating Keratoplasty

**Retrospective**


- Mean visual acuity improved from 1.05 (SD:0.54) to 0.17 (SD: 0.06) log MAR
- No graft complications, only prolapse, hyperemia or edema

**Prospective**

Alipour, F., Behrouz, M., Samet, B. Mini-scleral lenses in the visual rehabilitation of patients after penetrating keratoplasty and deep anterior lamellar keratoplasty

- Mean visual acuity improved from 0.85 to 0.17
- No graft complications, only prolapse, hyperemia or edema

### Post-LASIK Complications

Perac, E., Espino, G., et al. Post-LASIK Visual Quality With Connected Contact Lenses to Treat Irregular Cornea

- VA improved from logMAR 0.14±0.03 to 0.01±0.06
- Total HOAs improved from 1.06±0.44 to 0.23±0.14
- No statistically significant different in HDAs VA, or SQ before 1 year

**Retrospective**

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### Exposure Keratopathy

Chahal, J., Heur, M., Chiu, G. Eye & Contact Lens 2016

- VA improved from 56.54±29.75 to 24.98±21.23
- OSDI improved from 56.54±29.75 to 24.98±21.23
- Corneal staining decreased from 2.17±0.84 to 0.64±0.70
- Scleral lens can serve as an alternative to lid surgery

### Chronic Graft vs Host Disease


- VA improved from 72.6±20.1 to 21.1±10.9
- OSDI improved from 72.6±20.1 to 21.1±10.9
- 84% (66 of 79 eyes) showed decreased corneal staining
- Complete healing of 9/10 eyes (hematogenous keratitis), 9/9 eyes and epithelial defects (5/7 eyes)
Stevens Johnson Syndrome

- VA improved from 0.48 logMAR to 0.096 logMAR
- Visual function scores (VFQ-25) increased from 48 to 72 points
- NI in self reported general health

- VA improved from 1.0 logMAR to 0.17 logMAR
- ECT occurs at a higher-than-expected rate with SJS
- Contributory factors may include corneal microtrauma and MMPs

Prosthetic replacement of the ocular surface ecosystem: impact at 5 years

Joshua S Agranat, S. Nicole R Kito, Deborah S Jacobs
By Ophthalmol 2005
- Primary indication OSD (64 pts) followed by distorted corneal surface (57 pts)
- Continued device wear was 73.6% (89/121); Discontinued wear was 26.4% (32/121)
- Continued device wear with distorted cornea (84%) compared with OSD (64%). Wearing rate of 75% with GVHD compared with other OSD
- NEI-VFQ scores increased at 6 months with no decline at 5 years
- Higher NEI-VFQ scores at 5 years for those wearing device then those not wearing
- Improved VA is associated with continuation of wear at 5 years

Short-term Effect of Scleral Lens on the Dry Eye Biomarkers in Keratoconus

Gerarda Gruis, Maaike Jansen Kuster, Ria Martijn-Gil, Wies Blom
Optom Vis Sci 2010
- 26 pts split into 2 groups: ICRS and KCN s ICRS
- Both groups: No change to Schirmer test and TBUT, decreased OSDI scores and osmolarity (303 to 296 mOsm/l), increased MMP-9 (ICRS >KCN s ICRS)
- KCN s ICRS group had lower concentration of Ap4a
- ICRS group had no change to Ap4a

What Are the Effects of Scleral Lens Wear On:
- Tear film biomarkers
- Corneal curvature
- Corneal, conjunctival, episcleral, scleral thickness
- Optics and higher order aberrations
- Intraocular pressure
- Ocular surface temperature

Scleral lens influence on corneal curvature and pachymetry in keratoconus patients

Maaike Jansen Kuster, Niekke Smit, Esther Simone Visser, Saskia M. Imhof, Nayyin K. Tahrib
CLAE 2015
- Ave Corneal curvature was flatter (Ksteep 0.7D lower, Kflat 0.5D lower, Kmax 1.1D lower)
- Ave pachy was ±2.5% higher
Significant tissue thinning in all quadrants after 3 h (mean decrease in thickness -24.1 ± 3.6) did not return to baseline 3 h after lens removal (-16.9 ± 1.9).

Superior quadrant had largest tissue compression (-49.9 ± 8.5) and lens landing zone (scleral spur (-48.2 ± 5.7).

70% of compression occurred with conjunctiva and episclera.

Superior (nasal) mid-peripheral flattening (up to 0.08± 0.04 mm) especially with East Asian participants causing increased ATR astigmatism (up to 0.50D).

Decreased higher order aberrations (RMS -0.035 ± 0.046) including horizontal coma, vertical coma and spherical aberration.

Mean central IOP (13.9 ± 3.1 mm Hg) in study eye was not different from the controlled eye (13.9 ± 3.1 mm Hg) or in the same eye before lens wear (13.6 ± 1.9 mm Hg).

No difference in all temperature points before and after scleral lens wear.

No significant change in Schirmer test and TBUT.

Mean difference between observed and AS-OCT was:
- 115.0 microns OD
- 42 microns OS

Significant overestimation of CCC.
**Scleral Lens Tolerance after Corneal Cross-linking for Keratoconus**

Telko-Silence Vision, Nicolle Swart, and Henry G. Tabbara

- No change in VA, wear time, and subjective tolerance
- 61% needed fit and/or power change

**Mini-scleral Contact Lens for Management of Poor Visual Outcomes after Intrastromal Corneal Ring Segments Implantation in Keratoconus**

Ferraz et al, OPHTHALMIC SURGERY, LASER, & MICROINVASIVE SURGERY, 2016

- Mean UCVA 0.6±0.26 to BSVA 0.38 to BCVA 0.08±0.05 log MAR
- Total HOA decreased from 1.85±0.81 to 0.88±0.47

**Assessing Scleral Contact Lens Satisfaction in a Keratoconus Population**

Ben E. Reisman, Marie K. Waller, and Joel A. Johnson

- Past experience of soft, hard and hybrid designs with the majority wearing corneal GP lenses
- Ave wear time was 14 hrs (range 7-18)
- KC pts prefer comfort and vision while experiencing less dryness with ScCLs
- Most experienced occasional midday fogging

**Clinical Experience With PHOSE Fitting: Significance of Diagnosis and Age**


- Neither age or diagnosis affects ease of scleral lens use
- Ave number of devices: 5.3 ± 2.4, visits: 11.8 ± 4.4, length of fitting process: 183.8 ± 30.5 days (6 months)
- Wear time: 4.0 ± 4.0 week 1 to 8.0 ± 4.4 week 2, full time wear: 13.5 ± 11.8 days (2 weeks)
- I&R <5 min by week 5
- Difficulty: week 5 insertion 1.35 ± 0.61 removal 1.44 ± 0.50, score of 1 by week 5 for insertion and week 6 for removal

**Toric Peripheral Curves**


3 stabilization methods provided similar stability and simulated optical and visual performance compared with a spherical lens. Simple toric peripheral designed lens can be used with wave-front guided correction.

**Influence of Apical Clearance on Mini-Scleral Lens Settling, Clinical Performance, and Corneal Thickness Changes**

Fuchs, K., and Tan, T. J.

- Ave settling was 62.8 after 8 hrs with 80% occurred within 4 hrs
- 1.3% corneal swelling after 8 hrs
- Lower apical clearance settled less compared with high vault fits

**Scleral lens use in dry eye syndrome**

J. Ohy, Rodriguez, Korea Doores, and Shahid I. Allen

Outcomes
- Efficacy measured by improved OSDI, NEI-VFQ scores, and VA
- No difference based on cause of DES
- Wear time is over 16 hrs per day
- Predictors of success: 0.2 to 0.3 mm of corneal vault, 0.1 mm of limbal clearance without air bubbles
- Autologous serum tears together with scleral lenses
- Use with severe DES in conjunction with more aggressive treatment options
Ocular Surface Structure: Anatomy and Function

- Clinical observation
- Development of measurement methods
- Possible development of tools to allow for measurement
- Validation of said tools
- Collection (or identification) of baseline or control data
- Collection of data over time

Reviews of Ocular Disease

- Scleral stiffness for keratoconus: technology update
- Management of advanced corneal edema
- Advances in scleral lenses for refractive surgery complications

Reviews of Systemic Disease

- Scleral Stiffness
  - Studied post-mortem eyes
  - Primarily interested in posterior sclera, near lamina cribrosa
  - Diabetes increases scleral stiffness
  - Scleral stiffness also increases with age

Eye Cont Lens 2015

- Bandage and scleral contact lenses for ocular graft-versus-host disease after allogenic hematopoietic stem cell transplantation
- Superior Limbus Keratoconjunctivitis-like Inflammation in Patients with Chronic Graft-Versus-Host Disease

Scleral Shape

- Estimation of axial curvature of anterior sclera: correlation between axial length and anterior scleral curvature as affected by angle kappa
  - 24 eyes
  - Axial radius of curvature defined
  - Axial length, anterior chamber depth, white-to-white measurements are useful parameters for estimating ARC of sclera
Scleral Thickness

- Measured scleral thickness using anterior segment OCT
- Measured in 8 meridians from scleral spur in 74 individuals aged 40
- 1 mm increments to 6 mm
- Assessed intra- and inter-observer variability
- Mean scleral thickness was 725±46 microns
- SN meridian was thinnest, inferior was thickest
- Sclera was thinnest at scleral spur, thickest at 6 mm

PloS one 10(7): e0132902.

- 53 eyes (Caucasian subjects)
- Age range: 18-92 (mean: 48.6 years)
- Measured in 4 meridians (ST, SN, IN, IT) 2 mm from scleral spur
- Statistically significant differences between quadrants
- 475±81 ST, 463±64 SN, 571±84 IN, 511±80 IT
- Resembles spiral of Tillaux
- Scleral thickness increases with age

Comparison of Corneal Diameter and Anterior Chamber Depth Measurements Using 4 Different Devices

Mohak Shejari, MD,*, Ursula C. Lehmann, BSc,† and Thomas Kohnen, MD, PhD, FEBOP

1. 40 eyes of 40 subjects
2. Assessed AC depth and white-to-white measurements
3. Measurements were obtained with IOL Master, LenStar 900, Pentacam HR, and Visante OCT
4. Two independent measurements obtained on each device
5. All devices provided reliable and accurate measurements

The use of ocular anatomical measurements using a rotating Scheimpflug camera to assist in the scleral contact lens fitting process

Saud La Porta Weinert‡, Emilio Ambrosio Jr.‡, Cláudio Espinoza‡, Chancy C. Almeida‡,Ana Laura Melo Lima‡

1. Prospective, observational, non-randomized, non-comparative study
2. 63 eyes of 47 patients
3. Compared data from Pentacam (corneal elevation, thickness, density, and AC depth) to lens diameter and lens sagittal depth
4. Positive correlation between lens sagittal depth and AC depth in keratoconus
5. No statistically significant correlations noted in dry eye patients

Preclinical assessment of scleral lens as a reservoir-based ocular therapeutic system

Christian Labbé‡, Jonathan Vigne‡, Eric Désert†, Florian Lemaitre†, Didier Goux‡, Pierre-Jean Fisella‡

1. Assessed concentration of Ofloxacin in cornea, aqueous and vitreous in rabbits after 4 hours of scleral lens wear
2. Evidence of peripheral superficial keratitis was noted in treated eyes, but not in control eye

Anterior chamber depth measurements using Scheimpflug imaging and optical coherence tomography: Repeatability, reproducibility, and agreement

Qinwen Wang, MD, Xiaqun Deng, MD, Giuseppina Saez, MD, Hao Chen, MD, Yanfeng Song, MD, Chao Tan, MD, Xiaojun He, MD, and Hong Huang, MD

1. Compared intra-operator repeatability, inter-operator and intersession reproducibility, and agreement between Pentacam, Sirius, Galilea G3, and Visante AS-OCT
2. Evaluated 71 eyes of 71 patients
3. Found excellent intra- and inter-operator reproducibility
4. ACD agreement was reasonable between all devices

Medical Contact Lens Fitting


1. Assessed concentration of Ofloxacin in cornea, aqueous and vitreous in rabbits after 4 hours of scleral lens wear
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Scleral Lenses as Telescopes


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What do we still need to learn?

- Scleral Lenses and Conjunctiva
  - Thickness
  - Structure
  - Goblet cell density
- Scleral Lenses and the Cornea
  - Topographic changes
  - Corneal thickness/volume
  - Corneal nerve structure and function
- Scleral Lenses and Intraocular Pressure
  - Episcleral venous outflow
  - Schlemm’s canal

How do scleral lenses affect the anterior segment?

Conjunctival Prolapse

- Who is likely to experience this?
- Are there long-term negative consequences related to this issue? If so, what are they, and how often do they occur?
- How can we minimize or avoid entrapment?

Fluid Reservoir Debris

- What is it?
- How can we measure it?
- Who is likely to experience this?
- Does this affect vision (discrimination acuity, contrast sensitivity, glare)?
- Does this have any negative metabolic effects on the cornea?
- How can we prevent this?

What is the “ideal” fit?

- Lens Care
  - Surfactant cleaners (removal of surface debris without damaging lens surface)
  - Lens storage (preserved vs. non-preserved)
  - Application solution
- Wearing Schedules
  - As much as possible, or as little as possible?
  - Mid-day removal?
When should scleral lenses be used?

- Corneal Irregularity
  - Spectacles
  - Hydrogels/silicone hydrogels
  - Corneal RGP's
  - Hybrids
  - Piggyback systems
  - Scleral lenses

- Ocular Surface Disease
  - Lubricant drops
  - Punctal occlusion
  - Moisture chamber glasses
  - Topical medications
  - Systemic medications
  - Bandage contact lenses

Complications of Scleral Lens Wear

Patient Selection

- Characteristics of successful patients
  - Specific diagnoses?
  - Personality traits?
  - Physical characteristics?
  - Age?
  - Gender?
  - Expectations?
  - Entering visual acuity?
  - Degree of HOA?

Conclusion

- Explosive growth in research (quantity and quality) during the past two years
- Specific areas of study are being developed
- Variables that need to be controlled are being identified
- Multicenter studies on outcomes are not yet available
- There's plenty of room for growth in this area!