Scleral Lens Rapid Fire: Complications, Hypoxia, Post-Transplant, and Literature Update

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Scleral Lens Complications

- Lens management complications
  - Trouble with application, removal
  - Lens deposits, non-wetting, solution sensitivities
- Tear reservoir complications
  - Midday fogging, tear reservoir stagnation
- Corneal complications
  - Solution & fit-related epitheliopathies
  - Epithelial bogging
  - Corneal edema
  - Limbal bearing, edema, infiltrates, neovascularization
- Conjunctival/scleral complications
  - Impression, compression, staining, edema, prolapse
Lens Management: Application/Removal

The **WRONG** way to position the plunger on the lens.

The **CORRECT** way to position the plunger on the lens.
Lens Management: Cleaning & Handling
Tear Film Reservoir Complications

Midday Fogging

Baseline OCT

4h post application

8h post application
Tear Film Reservoir

Saline solutions

Alternate solutions
Corneal Complications

Preservative Toxicity

- Re-educate on PF solutions
- Evaluate tear exchange
- Consider medications & lens/ocular hygiene

Metabolic Toxicity

B. Severinsky et al 2014
Corneal Complications

Corneal Staining

- Increase SAG
- Steepen BC
- Increase intermediate and/or mid-peripheral clearances
- Increase diameter (along with SAG)

Etiology?
- Loss of glycocalyx layer
- Epithelial edema
- Osmotic imbalance
- Lack of epi cell sloughing

Epithelial Bogging

- Saline effect?
- Related to tear exchange?
Corneal Complications

Excess central clearance

- Decrease SAG
- Flatten BC
- Reduce intermediate and/or mid-peripheral clearances
- Reduce diameter (along with SAG)

Excess limbal clearance
Corneal Complications

**Limbal Bearing**

- Increase diameter
- Increase intermediate and/or mid-peripheral clearances

**Epithelial disruption**

**Limbal edema and neo**
Conjunctival/Scleral Complications: Compression, Edema and Prolapse

Impression Rings

Conjunctival Prolapse

Change limbal zone
Reduce diameter
Conjunctival/Scleral Complications: Edge Tightness & Lift
LOOK HIGH AND LOW

FOR THE PHYSIOLOGICAL IMPACT OF CENTRAL CLEARANCE IN SCLERAL LENSES
PREPARATION AND PRESENTATION

DR SANDRINE MALAISON-TREMBLAY

AMERICAN ACADEMY OF OPTOMETRY
2018
HYPOXIA

EFFECTS

- Decreased vision
- Limbal hyperemia
- Giant papillary conjunctivitis
- Epithelial keratitis
- Epithelial bogging
- Stromal swelling
- Stromal thinning
- Endothelial polymegatism
- Corneal acidosis
- Corneal abrasion
- Microcysts
- Decreased corneal sensitivity
Normal swelling induced overnight by eyelids
Goes away 1-2h post awakening

Oxygen permeability suggested to alleviate edema secondary to hypoxia
(Holden-Mertz / Harvitt-Bonanno)

Critical oxygen tension at cornea to avoid edema

Corneal oxygen consumption rate

NUMBERS

3.6 - 4.5%

24 - 35 Fatt

74 - 100 mmHg

5x10⁻⁵ - 1.05x10⁻⁴ mLO₂/cm³s
HOW TO MEASURE CORNEAL HYPOXIA?

- OBSERVABLE SIGNS
- MATHEMATICAL / THEORETICAL MODELS
- PACHYMETRY MEASUREMENTS
- IN VIVO
SIGNS

- Vertical striae (6.89% hypoxia)
- Increased pachymetry
MATHEMATICAL MODELS

CORNEAL OXYGEN CONSUMPTION

- Total oxygen consumption during CL wear
  - Eight-layer model with corneal regions where oxygen tension falls to zero
  - Corneal oxygen consumption rate \(= 4.48 \times 10^{-5} \text{ cm}^3 \text{O}_2/\text{cm}^3 \text{s} \) with SCL with Dk 20 (open eye) and 300 (closed eye)
  - CL with Dk 15 allows a 96% consumption rate

- Monod kinetics to describe local oxygen consumption rate
  - Max oxygen consumption rate \(= 1.05 \times 10^{-4} \text{ mL/cm}^3 \text{s} \)
  - Higher value of oxygen consumption rate than other studies
  - CL wear alters carbon dioxide transport to the air and restricts cornea metabolism
**OXYGEN TRANSMISSIBILITY**

- Theoretical oxygen tension with piggyback and scleral lens

  Resistance in series
  Tolerance criteria (tension) = 100 mmHg
  Oxygen consumption rate used = $5 \times 10^{-5}$ mL O$_2$/mLs
  Daily wear acceptable, extended wear questionable

- Values of oxygen transmissibility of scleral lens systems for various CL thicknesses, Dk and clearance

  Resistance in series
  Tolerance criteria (Dk) = 24 Fatt central cornea, 35 Fatt limbal area
  Dk between 10 to 36.7 depending on combinations
  Ideal fit: clearance 200 um, Dk 150, thickness 200 um

**MATHEMATICAl MODELS**

- Oxygen delivery with CL system

  Resistance in series
  Oxygen consumption rate used = $5 \times 10^{-5}$ mL O$_2$/mLs
  Tolerance criteria (tension) = 100 mmHg
  Criteria met with clearance 50 um, Dk 140, thickness 300 um

- Monod equations derived oxygen consumption values

  ($5 \times 10^{-5}$ cm$^3$O$_2$/cm$^3$s and $1.05 \times 10^{-4}$ cm$^3$O$_2$/cm$^3$s)
  Tolerance criteria (tension) = 100 mmHg
  Criteria met with lowest vault, highest Dk possible
  Oxygen tension and flux more sensitive to vault than Dk
PACHYMETRY

- Probe and topical anesthetic: 1.59% (67um) to 3.86% (267um) after 3h wear
- Scheimpflug imaging: 0.85% after 3h wear
  Less than 2% after 8h wear
- OCT: 1.18% 90 min after insertion
  1.3% after 8h wear
  1.51% after 5h wear
IN VIVO

- Noninvasive measurement of tear oxygen tension before and after CL wear
  Phosphorescence quenching of Pd-meso-tetra porphine by oxygen
  High oxygen = short phosphorescence
  Oxygen tension with highest Dk (51.9) = 78.7 mmHg

- Estimation of oxygen consumption by measuring oxygen tension with known CL Dk
  Oxygen-sensitive dye coated CL
  Mean oxygen tension with thin hydrogel CL = 30.6 – with hydrogel-silicone CL = 97.6

- Evaluation of relative partial pressure in oxygen (pO2) at corneal surface after scleral wear with clearance 200 and 400
  Oxygen electrode after exposure to calibrating gases
  pO2 w 200 = 9.07% - pO2 w 400 = 6.19%
  pO2 criteria to prevent hypoxia = 9.9%
  200 vs 400: ↓ 30% oxygen tension
Predicted maximal central lens thickness (um) to prevent hypoxia-induced corneal swelling in daily scleral lens wear (HM criterion) considering determined clearance values (L. Michaud et al. 2012)

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<th>Lens Dk</th>
<th>Clearance</th>
<th>100 µm</th>
<th>125 µm</th>
<th>150 µm</th>
<th>200 µm</th>
<th>250 µm</th>
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<td>125</td>
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WRAP UP

DISCREPANCIES

1. **Central clearance**
   - Influence of higher or lower post-lens tear film on hypoxia

2. **Induced hypoxia**
   - Discrepancy between theoretical models, oxygen tension and in vivo measurements
   - Tear mixing

3. **Parameters**
   - No clear consensus on data such as corneal thickness, anterior cornea oxygen tension for open and closed eyes, corneal oxygen consumption, aqueous humor oxygen tension, corneal oxygen transmissibility
**TEAR MIXING**

Tan, Zhou et al. (2018)

### Out-in method
- Fluorescein on bulbar conjunctiva
  - Monitoring first sign of dye under scleral lens
- 61.7% < 2 min
- 25% < 30 sec
- 33.3% = or > 5 min

### Fluogram technique
- Lens inserted with fluorescein in the bowl
- Modified slit lamp with filters for epifluorescence
- Decay
  - Fastest: superior quadrant
  - Slowest: Inferior quadrant
  - Faster in periphery than in the center
- Lens settlement may affect decay
- Lower vault = increased tear mixing
PHYSIOLOGY

EFFECTS OF HYPOXIA ON CORNEAL LAYERS
**EPITHELIUM**

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**Pachymetry fluctuations**
- 8h miniscleral CL wear
- $\uparrow$ 0-30 min then $\downarrow$ to reach minimum value at 480 min
  (Vincent et al. 2018)

**Epithelial bogging**
- Occurs when the cornea is soaked in saline for 10-12h of scleral CL wear
- Electrolyte imbalance
- Would be transient
- Troubleshoot: artificial tears with electrolytes
- Increased tear exchange

**Bullae**
- Mechanical stress on limbal cells
- Tight junctions disruption
- Fluid inflow
STROMA

PACHYMETRY FLUCTUATIONS

- Similar to total corneal thickness fluctuations
- ↑ 0-15 min
  - Stable 15-45 min (modified stromal metabolism)
  - Peak (1.18%) 90 min then ↓ to reach minimum value at 480 min
  - (Vincent et al. 2018)
- ↑ with plateau (1.65%) at 2h
  - (Tan et al. 2018)
- Layer where most of the swelling happens
ENDOTHELIUM

EFFECTS

- Polymegatism
- ↓ cell count
- “endothelial cell counts <1,000 cells/mm² should be handled with extra care and should not be fitted with scleral lenses to avoid edema” (Eef van der Worp. 2015)
CONCLUSION

- Promote fit with highest Dk and low tear reservoir
- Irregular cornea vs regular cornea
- Edema secondary to CL wear: 3h
- Discrepancy between calculation models and in vivo measurements
  - Tear mixing
  - Lens settlement
THANK YOU!

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References

Scleral Lenses
Fitting the Post-Transplant Cornea

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Assistant Clinical Professor
UC Berkeley School of Optometry
Disclosures

• Scleral Lens Education Society, Executive Board
• Gas Permeable Lens Institute, Advisory Board
• No financial disclosures
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Considerations for a Post-Transplant Cornea

• Challenging physical shape
  – Prolate vs. Oblate

• Potential increased risk of graft rejection and failure

• Patient selection and education
Prolate vs. Oblate

Post-Transplant Cornea: Oblate

Graft decentration and junctional knee height can present scleral fitting challenges due to their shape.
Prolate vs. Oblate

Prolate shaped lens on prolate shaped cornea provides ideal fit

Prolate shaped lens on \textit{oblate} shaped cornea may create non-ideal fit

Insufficient graft junction clearance

Excessive central clearance

Using an oblate design scleral on a post-transplant patient will better mirror the shape of the corneal surface and provide a more even tear reservoir between the lens and the eye.
Increased Risk of Graft Failure?

Major causes of graft failure:

1. Immunologic graft rejection (Leading cause of failure)
2. Endothelial decompensation
3. Ocular surface disease

Risk highest in the first year after transplantation

Risk drops to a low but steady rate over longer time periods
Immunologic Graft Rejection

• Normally corneal allografts have immune privilege, but this is easily disrupted by virtually any condition where neovascularization, inflammation, or trauma is elicited in the cornea.

• Observe graft size/location
  – Larger graft (≥8.5 mm) or decentered graft will be closer to limbal blood vessels.
Immunologic Graft Rejection

- Do sclerals have the potential to cause these non-ideal conditions that could lead to rejection?
  - Yes, especially if the fit is inappropriate or if patient is non-compliant
  - Care should be taken to avoid risk to a pre-graft cornea wearing sclerals
  - The post-graft cornea fit in a scleral lens must be monitored closely
Despite multiple attempts to contact this patient, they were lost to follow-up.

Over one year after dispensing the sclerals it was discovered the patient was sleeping in the lenses overnight regularly against recommendation, resulting in significant neovascularization.
NV Under Severe Conjunctival Prolapse

Prolapse: Benign or not?
Endothelial Decompensation

• It may be prudent to measure endothelial cell count on post-graft patients prior to initiating scleral fitting
  – Proceed with caution when <1000 cells/mm²

• Observe graft size
  – Smaller graft (≤7.0 mm) – 5x higher risk of endothelial cause of graft failure due to smaller pool of intact endothelial cells

• Endothelial cell loss is substantial in the 5 years following transplantation
Graft Edema after Scleral Lens Over-Wear
Graft Edema after Scleral Lens Over-Wear
Ocular Surface Disease

• Ocular surface disease can contribute to graft failure risk
• Improperly fit sclerals may result in ocular surface insult
Ocular Surface Disease

- Poor patient compliance or understanding of scleral lens care can result in solution toxicity

- Have the patient tell you in their own words how they are caring for their lenses

- Patient education and re-education is critical
Graft Rejection & Failure

<table>
<thead>
<tr>
<th>Signs of graft rejection:</th>
<th>Symptoms of graft failure:</th>
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<tbody>
<tr>
<td>• Epithelial or endothelial rejection lines</td>
<td>• <strong>Redness:</strong> graft rejection may be associated with eye redness</td>
</tr>
<tr>
<td>• Subepithelial infiltrates</td>
<td>• <strong>Sensitivity:</strong> rejection may cause increased sensitivity to light</td>
</tr>
<tr>
<td>• Unilateral AC reaction with keratic precipitate</td>
<td>• <strong>Vision:</strong> rejection can cause decreased vision, particularly foggy or cloudy vision</td>
</tr>
<tr>
<td>• Corneal edema</td>
<td>• <strong>Pain:</strong> rejection can cause discomfort, irritation or foreign body sensation</td>
</tr>
<tr>
<td>• Conjunctival hyperemia</td>
<td></td>
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<tr>
<td>• Post-op elevated IOP</td>
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</table>
Take Home Message

• While scleral lenses can be an excellent tool for managing post-graft, candidates must be monitored carefully and co-managed with surgeon appropriately.

• Appropriate fit assessment, corneal evaluation, and regular follow-up can help minimize risk for graft rejection and failure.

• Routinely re-educate patients to ensure proper lens care, handling, and compliance.
Thank You

Questions?
References

- Regis-Pacheco LF, Binder PS. What Happens to the Corneal Transplant Endothelium After Penetrating Keratoplasty? *Cornea* 2014;0:1–10.
Please silence all mobile devices and remove items from chairs so others can sit. Unauthorized recording of this session is prohibited.
Disclosures

- Allergan
- Alcon
- Alden Optical
- Acculens
- Bausch + Lomb
- Contamac
- CooperVision
- EveryDay Contacts
- Johnson & Johnson Vision
- Gas Permeable Lens Institute
- Novabay
- Ocusoft
- Paragon Bioteck
- Percept
- Scleral Lens Education Society
- Science Based Health
- Shire
- Sjogren's Syndrome Foundation
- STAPLE program
- SynergEyes
- Visioneering Technologies
What does the literature say?
Scleral Lenses Reduce the Need for Corneal Transplants in Severe KCN

- Evaluated success and failure rates of scleral lens correction in severe KCN
- All patients with KCN
- Evaluated between January 2010 and December 2014

- 75 eyes with maximum keratometry values ≥ 70 diopters
  - (determined by Scheimpflug tomography sagittal curvature map)
Scleral Lenses Reduce the Need for Corneal Transplants in Severe KCN

- Scleral lenses prescribed in 51 of 75 eyes
- ★ 40 of 51 eyes with severe KCN that would otherwise have undergone transplant surgery were successfully treated with long-term scleral lens wear
- ★ Indication for keratoplasty was more than halved in the KCN population

Keratoconus and Personality – A Review

- Literature search
- Review of 15 articles
- Patients with KCN tend to score differently on personality scales compared with normal controls

- Literature fails to substantiate a unique "keratoconic personality"

Keratoconus and Personality – A Review

• KCN patients have more dysfunctional coping mechanisms that specifically alter their interaction with health care provider.

• May account for the persistent clinical impression of less respectful, conforming, and cooperative.

• ★...the stage of life at which KCN commonly presents plays a crucial role in personality and coping mechanism development that significantly affects behavioral patterns and the relationship with caregivers.
Quality of Life in Patients Wearing Scleral Lenses

- Evaluated the improvement of QOL with scleral lenses in KCN or the treatment of astigmatism after penetrating keratoplasty
  - Retrospective study
  - Patients failed to adapt to RGP lenses
  - QOL before and after scleral lens adaptation

Quality of Life in Patients Wearing Scleral Lenses

• 47 patients (83 eyes) fit with scleral lenses on one or both eyes
• 56 eyes with KCN
• 27 post-keratoplasty eyes

• NEI-VFQ 25 scores with scleral lenses were significantly higher than those without scleral lenses.
• ★ Scleral lenses showed significant improvement in quality of life for patients who had failed or are intolerant to conventional rigid gas permeable contact lenses.
• Scleral lenses are an alternative or a step prior to surgery

The Lens Haptic

- Large Diameter
  - More scleral asymmetry/toricity
- More scleral toricity
  - More advanced haptics needed for alignment
The Lens Haptic

- Profilometry
  - Advanced scleral imaging exists to aid in understanding scleral shape
    - Eaglet ESP
    - Precision Ocular Metrology SMap3D
The Lens Haptic

- Improve Haptic Alignment
  - Spherical (Common)
    - Same Curve 360
  - Toric (Common)
    - Vertical vs Horizontal
  - Quad (Less Common)
    - Quadrant independant
  - Octo (Rare)
    - Eight Sub Meridian
  - Elevation Specific (Very Rare)
    - Anything anywhere

Images: John Gelles, OD

<table>
<thead>
<tr>
<th>Group</th>
<th>Pattern Description</th>
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<td>1</td>
<td>Spherical</td>
<td>8 (5.7%)</td>
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<tr>
<td>2</td>
<td>Toric-Regular</td>
<td>40 (28.6%)</td>
</tr>
<tr>
<td>3</td>
<td>Asymmetric High or Low Points</td>
<td>57 (40.7%)</td>
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<tr>
<td>4</td>
<td>Periodicity different from 180°</td>
<td>35 (25%)</td>
</tr>
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</table>

**65.7%**

Table 1 Scleral Surface Patterns Observed in 140 Scleral Lens Patients

Courtesy of Greg DeNaeyer, OD, FAAO, FSLS
Scleral Shape

• 4 primary categories of scleral shape
• Measurement of the scleral allows for more efficient and accurate determination of lens design
• Results suggest that the majority of eyes may benefit from custom back surface haptics beyond a toric design

IOP and Scleral Lenses

• In 2016, McMonnies hypothesized that scleral lenses may increase IOP during lens wear due to compression of the episcleral veins.¹

• Can scleral lenses apply significant pressure on the episcleral veins and aqueous humor drainage to inhibit aqueous outflow, thus elevating IOP?

**IOP and Scleral Lenses**

- Nau et al evaluated IOP after two hours of small-diameter scleral lens wear in 29 neophyte healthy subjects.²
- 15mm Jupiter scleral lens
- Fit on one study eye
- Lens worn for two hours
- IOP measured by pneumatonometry (Model 30 Classic: Reichert) in both eyes
  - Measured on central cornea and peripheral sclera
- In healthy, neophyte eyes, scleral lens wear did not increase IOP after two hours.

IOP and Scleral Lenses

- Changes in IOP after scleral lens wear with an irregular cornea 16.5mm Paragon Vision Sciences scleral lens design.\(^3\)

- First study - IOP of 7 subjects before and three hours after scleral lens wear with the Ocular Response Analyzer (Reichert)

- Follow up study - IOP in 5 subjects before and 8 hours after scleral lens wear with a non-contact tonometer (TX-20P, Canon)

IOP and Scleral Lenses

- Decreases in IOP were found after scleral lens wear that were consistent with normal diurnal fluctuations in IOP in the control eye.

- The authors suggested that short-term wear of scleral lenses does not elevate IOP, despite superficial tissue compression near the scleral spur.4

IOP variation associated with the wear of scleral lenses of different diameters

• Prospective, randomized study\textsuperscript{5}
• 22 patients
• No significant diurnal variations in baseline IOP
• Transpalpebral IOP before and after scleral lens wear (Diaton tonometer)
  • 2 diameters, 15.8 mm (L1) and 18.0 mm (L2)
    – Lenses same design, thickness, and material
• Baseline and after 4-5 hours of wear
• Exercice and nutrition were controlled

\textsuperscript{5} Michaud L, Samaha D, Giasson CJ. Intra-ocular pressure variation associated with the wear of scleral lenses of different diameters. \textit{Cont Lens Anterior Eye}. 2018 Jul 24. [Epub ahead of print]
Results

IOP vs time and diameter

No IOP increase in 4 (19%) with L1 and 1 (4%) with L2
IOP rise > 10 mmHg: 4 (19%) L1 and 3 (14%) with L2
Highest: +15 mm Hg (L1) and +17 mm Hg (L2)

Back surface K readings

Front surface K readings

Slide credit Langis Michaud
Results – Part II

Corneal swelling

<table>
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<tr>
<td>AC depth (mm)</td>
</tr>
<tr>
<td>AC volume (mm3)</td>
</tr>
<tr>
<td>IC angle (degrés)</td>
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<tr>
<td>MSD lens 18mm</td>
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<tr>
<td>AC volume (mm3)</td>
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<tr>
<td>IC angle (degrés)</td>
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</table>
• IOP difference was statistically significant based on time but not lens diameter
• Anterior segment tomography using Oculus Pentacam taken prior to and after lens removal.
• Decrease in anterior chamber volume (L1: -1.53 + 7.61 mm³; L2: -3.47 + 6.4 mm³)
• Increase in corneal thickness (+2.1% with L1 and L2)
• Lens diameter does not influence outcomes

• Limited tear exchange with scleral lenses
• Lens compression on the conjunctiva
• NET suction effect
• Increased tightening?
• Leads to increased IOP?
Questions and Future Research

• Caution advised when fitting scleral lenses in patients with
  – Glaucoma
  – Ocular hypertension
  – Glaucoma suspect
  – Status post a filtration device
• Establish baseline parameters
• Check IOP at every visit

• Should different scleral lens designs be manufactured that rest differently on the scleral conjunctiva to prevent IOP elevation?
• Should scleral lenses not be fit in patients with glaucoma?
• Are other parameters such as ocular blood flow or corneal hysteresis valuable in this population?
• Numerous future studies need to be performed.
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