SCLERAL LENSES 10 YEARS AFTER: WHERE ARE WE?

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DISCLOSURES

DR MICHAUD
- HONORARIUM OR RESEARCH FUND RECEIVED
  - BAUSCH & LOMB
  - COOPER VISION
  - VIT NATURAL EYES
  - SYNERGEYES
  - LABORATOIRES BLANCHARD

DR BRAZEAU
- HONORARIUM OR RESEARCH FUND RECEIVED
  - BLANCHARD LABS

SL ARE AMAZING

- USED AS TREATMENT FOR SEVERAL OCULAR SURFACE CONDITIONS
- CONSIDERED A REHABILITATORY DEVICE FOR OCULAR SURFACE COMPROMISE (IE. DRY EYE)
SL ARE AMAZING

- SL provide a rigid refractive surface that allows retinal image formation through distorted corneas (i.e., keratoconus)
- Large optic zone = improved vision
- Stability = better centration - presbyopia

SCLERAL LENSES BENEFITS

- STABLE, PREDICTABLE VISUAL ACUITY
- IMPROVED COMFORT VS OTHER MODALITIES
- TEAR FLUID LAYER:
  - MOIST MICRO-ENVIRONMENT, PROTECTIVE, REFRACTIVE
- REDUCED LENS MOVEMENT ON THE EYE:
  - IMPACT ON COMFORT (LENS TO LID INTERACTION) AND OPTICS (CENTRATION)

- IRREGULAR CORNEAS
- DISEASED EYES
  - INCLUDING DRY EYE SYNDROME
- NORMAL CORNEAS
  - IMPROVES DYSCOMFORT OF DISEASE OF GLOBULAR BULB
  - HIGH REFRACTIVE ERRORS
  - ARISTOCRATER (UP TO 3.25 WITH A SPHERICAL)
  - PREVENTION (BILINGUAL WITH ARISTOCRATER)
  - SPORTS
  - ALLERGY CONTROL

Known applications

New trend
LESSONS FROM THE LAST 10 YEARS: SCLERAL LENSES LIMITATIONS

- HANDLING
  - Application and removal
- LEARNING CURVE
  - Fitting and troubleshooting vs other modalities
- PHYSIOLOGICAL IMPACT
  - Optimal oxygenation
  - Corneal hypoxic stress
  - IOP
- REFRACTIVE
  - HOAS
  - High refractive errors lenses (mass and thickness)

THE SCLERAL LENS It is not without complications...


Risk / Benefits: Evaluate Options
10 YEARS AFTER: MID-DAY FOGGING, STILL NO.1 ISSUE

ISSUE #1: MID-DAY FOGGING

CURRENT THINKING IN MDF

- Sequestered lipids, proteins, cell fragments, make-up, mixture of all these components (variable)
- Can mostly be managed by lens fit and hygiene
- No apparent increase in inflammation

Visual frustrating!

Necessitates removal and refreshing of solution 2-5+ times per day

Most often affects people with ocular surface disease (ie. MGD)
MECHANISMS OF MDF

• OCULAR SURFACE DISEASES, DYSFUNCTION (IE. ALTERED INFLAMMATORY RESPONSE)

• MECHANICAL DISTURBANCE OF CONJUNCTIVAL TISSUE (IE. CHANGE IN BV PERMEABILITY)

• SCLERAL LENS SUCTION EFFECT

CURRENT THINKING IN MDF

Main Culprits:
• Central clearance – limit to 240 um (Nichols manuscript)
• Limbal clearance – lower it (<75 um)
• When to limit tear exchange, and when to enhance it?
• Lens design changes
• Diameter
• Toric peripheral curves
• Lens removal and reapplication – pros and cons

MANAGEMENT OF MDF

Primary Management Strategies:
• Reduce clearance
• Loosen/toric landing zone
• A well aligned (haptic) is the least likely to induce MDF
• Change solution…
**MANAGEMENT OF MDF: LENS DESIGN**

- Personal hygiene therapies (change along with fit!)
  - Eyelid health
  - Treatment of allergies/dry eye
  - Eyewash
  - Waiting to apply lenses in AM

**MANAGEMENT OF MDF: APPLICATION SOLUTION**

- Preservative free artificial tears
- Autologous Serum – severe OSD
ADJUNCT THERAPIES
- Care regimen
- Lubrication during lens wear
- Medication in case of ocular surface disease
- Do lens coating help?

WHAT HAPPENS TO THE CORNEA?
- EPITHELIAL LEVEL
  - OXYGEN CONSUMPTION
  - EPITHELIAL BOGGING – INFLAMMATORY?
- STROMA
  - CORNEAL SWELLING
- ENDOTHELIAL
  - BLEBS

10 years after: hypoxic stress is confirmed!

A theoretical approach
- Considering available materials
  - DK of 100 to 170
  - Various lens thicknesses
    - 250-300 um
    - Post-lens tear thickness
      - 100-400 um
- PREDICTED OUTCOME:
AVERAGE SCLERAL LENSES

- TRADITIONAL CT
  - .3MM THICK (300 MICRONS) TO .6MM THICK (600 MICRONS)
  - RANGES GREATLY BASED ON RX
  - INDUSTRY CONCERN OF FLEXURE UNDER .3MM
  - AVERAGE CT = .45MM

- TRADITIONAL VAULTS
  - MULTIPLE FITTING SETS AND LECTURES REVIEWED
  - LOW VAULT = 100 MICRONS
  - HIGH VAULT = 600 MICRONS
  - AVERAGE = 300

- TRADITIONAL MATERIAL
  - LAGADO TYRO 97 = DK 97
  - BOSTON XO = DK 100
  - CONTAMAC OPTIMUM EXTRA = DK 100
  - AVERAGE DK OF 100

- TRADITIONAL HAPTICS
  - NO BLANCHING OF CONJUNCTIVAL VASCULATURE
  - VARIED BASED ON GUIDE
  - SOME STATE QUADRANT OF BLANCHING OK
  - DK/T = 12

AN IN VIVO STUDY

** RELATIVE PO2 AT CORNEAL SURFACE EXPECTED FROM THESE DK/T WERE ESTIMATED AS FOLLOWS:**

\[ EOP (\%) = -19.6 \cdot \exp (-0.029 \cdot \text{DK/T}) + 19.8 \quad (R^2 = 0.97) \]

- MINIMAL LEVEL TO AVOID HYPOXIA = 9.9%
- CALCULATED VALUES OF DK/T WERE INPUT INTO THIS EQUATION

<table>
<thead>
<tr>
<th>DK/T</th>
<th>EOP (%)</th>
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<tbody>
<tr>
<td>12</td>
<td><strong>8.52±0.51</strong></td>
</tr>
<tr>
<td>8</td>
<td>6.37±0.28</td>
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<table>
<thead>
<tr>
<th>Average clearance (um) (SD)</th>
<th>239.7±34.7 434.5±33.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average lens thickness (um) (SD)</td>
<td>315.1±0.7 309.5±1.3</td>
</tr>
<tr>
<td>Estimated DK/t (x 10^-9) (cm/sec)(ml O2/ml X mmHg)</td>
<td>19.1±1.6 13.0±0.7</td>
</tr>
<tr>
<td>Predicted pO2 (%)</td>
<td><strong>8.52±0.51</strong> 6.37±0.28</td>
</tr>
<tr>
<td>Measured pO2 (%) (SEM)</td>
<td>9.07±0.86 6.19±0.87</td>
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**Epithelial bogging or “Water-logged epithelium”** occurs when cornea is in saline for 10-12 hrs/day
- Similar to skin wrinkling when put in water for extensive period of time
- Electrolyte imbalance or altered homeostasis stimulate sympathetic nerve response

**In response:** cells are swelling /increase their surface
- Slight adaptation, bogging reduction, can happen over weeks/months

**Troubleshooting**
- Artificial tears with electrolytes (SH)
- Increase tear exchange (flatter pc's) and oxygen delivery
- Hyperosmotic agent – short term ; cyclosporine – long term
HYPOXIC STRESS

• Hypoxic environment can induce leukocyte infiltration
• Oxygen tension at corneal level, during sleep = 2-4% vs 21% open-eye
• Same level of oxygen tension under a scleral lens
• Therefore the hypoxic environment under a SCL somewhat mimics the closed eye environment and lead to leukocyte infiltration = fogging

CLINICAL IMPACT

This study also showed that central Scl clearance was associated with the presence of post-lens tear film fogging. In particular, for every 500μm increase in Scl central clearance, there was a 2.24 times higher odds of presenting with post-lens tear film fogging. This finding supports the recommendation of minimizing central clearance, sometimes recommended to be less than 200 μm.5

TIME COURSE

Cumulative Scl lens induced central clearance is shown in scatter. The average central central and total central thickness decreased rapidly following lens insertion and peaked after 60s, while central epithelial thickness gradually decreased throughout late mean consistent with normal basal values. A greater initial central epithelial thickness resulted in reduced oxygen delivery to the cornea, which had minimal electron transport upon healthy eyes, however, markedly central oxygen delivery may be important in eyes with uncorrected astigmatism or elevation.
SCLERAL LENS AND ENDOTHELIAL CELLS

"ENDOTHELIAL CELL COUNT OF LESS THAN 800 CELLS/MM2 IS WHERE THE PROBLEMS MAY ARISE (SINDT 2010A), AND 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. A GUIDE TO SCLERAL LENS FITTING (2 ED.)

EXHAUST OTHER OPTIONS FIRST:

A NEW FINDING: BLEBS !!!

BEFORE                   AFTER
LENS WEAR                     LENS WEAR min)
18 mm lens
BXO2
320 um thick
200 /400 clearance

OTHER CONTRIBUTING MECHANISMS ?

- TEAR EXCHANGE
  - IMPAIRS DURING LENS SETTLENG
  - PAUGH, EYE & CONTACT LENS: MARCH 2018 - VOLUME 44 - ISSUE 2 - P 97-101
  - 0-30 MIN 0.07 (±0.6) %/MIN
  - 30-60 MIN 0.04 (±0.6) %/MIN
  - NON-CL WEAR 34.17 (±15.9) %/MIN
  - SI-HY CL (0-30) 6.09 (±2.8) %/MIN.

- TEAR MIXING (MENG LIN, GSLS 2018)
  - NOT CONTRIBUTING A LOT
  - IMPROVED IF CLEARANCE IS REDUCED
IMPACT ON THE SELECTION OF THE LENSES

- THERE ARE OPTIONS TO ALLEViate HYPOIGRA.
  - TO FIT LENSES WITH REDUCED THICKNESS
  - TO USE PLANS LARGER THAN NEEDED (COMPLICATED ALGORITHM POSSIBLE)
  - TO MODULATE SCLERAL LENS THICKNESS BASED ON INDIVIDUAL CORNEAL CHARACTERISTICS

Most probably feasible with smaller diameter scleral lenses
OR
Customized larger scleral lenses
... all manufactured with highest DK material

10 YEARS LATER: NEW FINDINGS
VISUAL QUALITY AND SCLERALS

RESIDUAL ASTIGMATISM: KC AND GPS

- 76 EYES WITH PARACENTRAL CONES / 80 CENTRAL CONES
- SUBJECTS: 22.1 YEARS OLD
- -3.50 ± 1.60 D REFRACTIVE ASTIGMATISM
- FITTED WITH 3 POINT TOUCH APPROACH GP LENSES
- RESIDUAL ASTIGMATISM: -0.75D ± 0.37
- NO EFFECT FROM THE CONE LOCATION (CENTRAL OR PARACENTRAL)

Cone location and correction of keratoconus with rigid gas-permeable contact lenses.
Nejabat M1, Khalili MR, Dehghani C.
MOST LIKELY COMING FROM HOA !!!

- KC Patients show reduced corrected vision vs normal population
- This may be attributed to the presence of HOA
- Correction of HOA up to 6th order of Zernike restore VA in KC patients
- Reduced VA in GP fitted KC patients result from uncorrected HOA

HOA AND POSTERIOR CORNEAL SURFACE

- 24 normal vs 28 KC eyes
- HOA evaluated with Scheimpflug on both corneal surfaces
- Total HOA Ant/Post: 4.34 / 1.09 KC 0.46/0.15 control
- HOA in KC: coma > trefoil > negative SA
- Anterior surface compensates in part for posterior surface HOA
- Residual astigmatism in patients with KC wearing rigid gas permeable lenses can be estimated by measuring HOA from the posterior cornea

OBLATE DESIGN MAY HELP

Kozy et al. . Ohio state Study
Use of small RGP reverse geometry vs regular design on KC patients
Significant reduction of coma
Significant improvement of VA
Significant reduction of minus power
SCLERAL LENSES : SIMILAR FINDINGS

- HOA NOT TOTALLY COMPENSATED WITH REGULAR SCLERAL LENSES
- WAVE-FRONT GUIDED DESIGNED LENSES REDUCE HOA SIGNIFICANTLY
- CONSEQUENTLY, VA IS IMPROVED IN ALL PATIENTS

Wavefront-guided scleral lens correction in keratoconus.
Marsack JD1, Ravikumar A, Nguyen C, Ticak A, Koenig DE, Elswick JD, Applegate RA.

Mean uncorrected higher-order RMS measured over a 6 mm pupil while wearing the spherical equivalent scleral contact lens (light gray bars) and wfgSCL(gray bars). Age-matched higher-order RMS from Applegate et al. is also presented (dark gray bars).

HOA AND LENS CENTRATION (IOL)

- LENS CENTRATION INFLUENCES THE PRESENCE OF HOA
- 2ND ASTIGMATISM INCREASES BY 0.18 TO 0.26 UM / MM OF DECENTRATION
- COMA INCREASES BY 0.19 TO 0.39 UM /MM OF DECENTRATION
- 0.7 MM LENS DECENTRATION INCREASES STREHL RATIO X 2.2 TO 3.2 TIMES VS CENTERED LENS
- SIGNIFICANT IMPACT FROM LENS DECENTRATION
- RESULTS CAN BE EXTRAPOLATED TO CONTACT LENSES

Effect of intraocular lens decenteration on image quality tested in a custom model eye.
Pérez-Merino P1, Marcos S2.

LENS DECENTRATION

CAUSES:
- LID FORCES
- LENS MASS (EXCESSIVE CT)
- EXCESSIVE LIMBAL CLEARANCE
- POOR ALIGNMENT BETWEEN LANDING ZONE AND SCLERA
- CORNEAL / SCLERAL SHAPE FACTORS

PHYSIOLOGICAL IMPACTS
- LENS BEARING ON THE NASAL SUPERIOR CORNEA
- CORNEAL STAINING
- HIGHER DISCOMFORT
THE OPTICAL IMPACT

- Decentered lenses induce:
  - Base down prism
  - Coma and spherical aberration with moderate to larger pupils
  - Decentration of add zones with multifocals
  - Residual astigmatism

UNIVERSITY OF MONTREAL

HIGH ORDER ABERRATIONS WITH AND WITHOUT SCLERAL CONTACT LENSES IN PATIENTS WITH KERATOCONUS

U de M study

**Discussion**
- 60% or higher reduction for high order aberrations in 28 eyes
- 31 eyes for coma and 30 eyes for trefoil
- Better improvement for those with high HOA uncorrected

**Conclusion**
- Scleral contact lenses greatly minimize high order aberrations in patients with keratoconus
- In some patients, HOA remains at a higher level and may disturb visual acuity
- Sub-analysis: early cones, with better than 20/40 VA in glasses
SCLERAL LENSES: RESIDUAL ASTIGMATISM

Suggested etiologies:
- Lens flexure
- Tear layer profile - Lens decentration
- Lenticular astigmatism
- High corneal astigmatism

LET'S TAKE A LOOK AT LENS " FLEXURE "

• LENS FITTED WITH SMAP 3D – TORIC PC'S AS NEEDED
• VARIATION OF LENS THICKNESSES AND CLEARANCE
• DEMOGRAPHICS: F (70%); M (30%); 23 Y.O.; NON SCLERAL LENS WEARERS, WASHOUT 72H00

<table>
<thead>
<tr>
<th>Parameters</th>
<th>LENS A</th>
<th>LENS B</th>
<th>LENS C</th>
<th>LENS D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness</td>
<td>347.3</td>
<td>350.45</td>
<td>266.8</td>
<td>260.0</td>
</tr>
<tr>
<td>Clearance</td>
<td>98.2</td>
<td>226.3</td>
<td>96.1</td>
<td>240.6</td>
</tr>
<tr>
<td>Power</td>
<td>-0.25</td>
<td>Plano</td>
<td>-0.23</td>
<td>Plano</td>
</tr>
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</table>

INDUCED ASTIGMATISM

<table>
<thead>
<tr>
<th>Parameters</th>
<th>LENS A Vs B</th>
<th>LENS A Vs C</th>
<th>LENS C Vs D</th>
<th>LENS B Vs D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere</td>
<td>-0.66 ± 1.68</td>
<td>-3.35 ± 2.33</td>
<td>-0.63 ± 1.69</td>
<td>-3.40 ± 2.37</td>
</tr>
<tr>
<td>Cyl</td>
<td>-0.39 ± 0.29</td>
<td>-0.76 ± 0.34</td>
<td>-0.65 ± 0.34</td>
<td>-0.64 ± 0.22</td>
</tr>
<tr>
<td>Axk</td>
<td>86 ± 15</td>
<td>93 ± 16</td>
<td>87 ± 16</td>
<td>91 ± 16</td>
</tr>
<tr>
<td>Over K</td>
<td>0.43 ± 0.13</td>
<td>0.29 ± 0.14</td>
<td>0.30 ± 0.18</td>
<td>0.33 ± 0.18</td>
</tr>
<tr>
<td>VA (DE)</td>
<td>0.05 ± 0.05</td>
<td>0.03 ± 0.04</td>
<td>0.06 ± 0.07</td>
<td>0.06 ± 0.07</td>
</tr>
</tbody>
</table>

p
- 0.07
- 0.176
- 1.00
- 0.211
TROUBLESHOOTING

TO DO
• REEVALUATE THE FIT ONCE THE LENS IS ALIGNED
• DESIGN PERIPHERAL CURVES IN ALL QUADRANTS (NOT ONLY THE PRINCIPAL MERIDIANS)
• REDUCE LENS MASS
• REDUCE LIMBAL CLEARANCE
• REDUCE LENS DIAMETER
• CREATE DESIGN MAY HELP
• IF NOT, CONSIDER OTHER OPTIONS
• HAVE WAVE-FRONT CORRECTING OPTICS WHEN IT WILL BE AVAILABLE

NOT TO DO
• INCREASE LENS THICKNESS
• RX PRIOR TO THE LENS WITHOUT CHECKING WITH LOOSE LENS BEFORE

10 YEARS LATER: NEW FINDINGS
INTRA-OCULAR PRESSURE AND SCLERALS

UNDERSTANDING THE FLUID LAYER COMPONENT
• RESERVOIR IN SERIES
• VOLUME COMPRESSION
• SUB- ATMOSPHERIC PRESSURE
• INCREASED TIGHTENING OVER TIME
THEORETICAL ASPECTS

- MCMONNIES RAISED THE HYPOTHESIS THAT SCLERAL LENSES MAY INDUCE IOP ELEVATION DURING LENS WEAR (MCMONNIES, 2016)
- EPISCLERAL VEINS COMPRESSION (MCMONNIES, 2016A)
- SCHLEMM'S CANAL DEFORMATION BENEATH THE LANDING ZONE (NAU, 2016)
- BEARING ZONES MAY APPLANATE OCULAR SURFACE
  - AREA AND DEPTH OF INDENTATION: 2ND TO DEGREE OF FITTING TIGHTNESS
  - HIGHER RISK: THINNER SCLERA (MCMONNIES, 2017); SMOOTHER SCLERA (NAU, 2016); SMALLER LENSES (NAU 2016)
- AREA AND PRESSURE APPLIED ARE THE KEY FACTORS, NOT RIGIDITY (NAU, 2016)

IS GLAUCOMA A RELATIVE CONTRAINDICATION TO SL WEAR?? THEORETICAL ASPECT

Compressive landing zone on the conjunctiva

GLAUCOMA PATIENTS WITH A/C SURGERIES

Without SL

With SL


International Glaucoma Society
CASE CONSIDERATIONS: PATIENT CHARACTERISTICS

Risks
- Risk of progressive myopia
- Glaucoma risk

Benefits
- Quality of life
- Comfort
- Vision

RESULTS

IOP VS TIME AND DIAMETER
- NO DIURNAL VARIATION

<table>
<thead>
<tr>
<th>Time</th>
<th>Average IOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Li</td>
<td>15.8 mmHg</td>
</tr>
<tr>
<td>L2</td>
<td>18.0 mmHg</td>
</tr>
</tbody>
</table>

No variation 4 (19%) 3 (14%)

> 10 mm Hg 4 (19%) 3 (14%)

Average 5 mm Hg 5 mm Hg

Highest +15 mm Hg +17 mm Hg

DISCUSSION

- Miller and Carroll found a sub-atmospheric pressure of 5 to 18 mm Hg.
CLINICAL OUTCOME

- \(+\) LIMITED TEAR EXCHANGE
- \(+\) LENS COMPRESSION ON THE CONJUNCTIVA
- \(-\) NET SUCTION EFFECT
- \(+\) INCREASED TIGHTENING
  - \(\rightarrow\) AGREEMENT WITH QUADRANT SPECIFIC TORIC HAPTICS
- \(+\) INCREASED IOP

Recommended clearance of 200 um, with larger lenses ...

DISCUSSION

- IOP VARIED BUT CORNEA WAS KEPT THE SAME
- LENS DIAMETER DOES NOT INFLUENCE THE OUTCOME
  - SCERR IS STIFFER CLOSER TO THE LIMBUS (ELSHEIKH ET AL., 2010)
- PRIMARY FUNCTIONAL DIAMETER (PFD)
  - \(\rightarrow\) WHERE THE LENS LANDS
    - IN OUR STUDY, PFD = 13.8 (15.8 OAD) AND 14.4 (18.0 OAD)
- THERE IS NO SNOWSHOE EFFECT
  - CONTRADICTS NAU'S HYPOTHESSES ABOUT SMALLER LENSES AS A RISK FACTOR
  - BOTH LENSES COMRESS THE CONJUNCTIVA IN THE SAME AREA

ANOTHER WAY OF EVALUATION IOP VARIATION EFFECT

- Bruch's Membrane Opening (BMO), Termination of Bruch's Membrane at the Optic Nerve Head
- Minimum Rim Width (MRW), Shorted Distance from the BMO to the Inner Limiting Lamina (Also termed BMO-MRW)
IMPACT ON LENS DESIGN

- SMALLER VS LARGER DIAMETER
- ALLEVIATE HYPOXIA
- NO IMPACT ON IOP
- TORIC HAPTICS NEEDED
- TO LIMIT LENS TIGHTENING EFFECT
- MATERIAL SELECTION
- HIGHER DK AVAILABLE
- TEAR EXCHANGE
  - IF POSSIBLE
  - VS DEBRIS

CONCLUSION

- SCLERALS, 10 YEARS LATER, STILL CONTRIBUTE TO CHANGE PATIENT'S LIVES AND TO IMPROVE QUALITY OF LIFE
- BUT WE UNDERSTAND MORE THEIR BEHAVIOUR ON THE EYE AND THEIR IMPACT
- NO LONGER THE #1 OPTION ACROSS THE BOARD
  - LIMITATIONS EXIST
- MORE RESEARCH NEEDED
  - ESPECIALLY WITH NEW CUSTOMIZED, QUADRANT SPECIFIC, TORIC HAPTICS (TIGHTENING EFFECTS)