Clinical Considerations with Silicone Hydrogel Lenses

Maurice J Wilson, OD

Agenda
- The science behind the lenses
- Oxygen
- Surface
- Design
- Lens care and silicone hydrogel lenses
- Comfort & adaptation issues

The Science Behind the Lenses

- HEMA-based materials
  - Positives
    - Easily fabricated into CL’s
    - Relatively cheap to produce
    - Highly flexible
    - Dimensionally stable to changes in pH & temp.
  - Negatives
    - Reliance on H2O to transport O2
      - Limitation to amount of O2 transmitted to cornea
      - Corneal oxygen deficiency

O2 transport – HEMA materials

Dk/t and H2O

- Primary means of ↑ Dk/t is to ↑ H2O
- H2O has limited ability to dissolve & transport O2
- Dk of H2O approx. 80
  - “100% H2O lens” Dk = 80

Corneal Oxygen Deficiency

- Clinical signs
  - Conjunctival injection
  - Neovascularization
  - Refractive error shift (myopic shift of ≥ 0.50 D)
  - Corneal edema
  - Increased bacterial binding
  - Keratometry/topographical changes and distortion
  - Limbal redness
  - Corneal staining
  - Corneal neovascularization
  - Corneal distortion
  - Endothelial polymegathism, pleomorphism & ↓ cell density
  - Increased corneal thickness
Corneal Oxygen Deficiency

- Patient symptoms
  - End-of-day discomfort, itching or dryness
  - Reduced wearing time
  - Lens awareness
  - Sore, irritated eyes
  - End-of-day dryness
  - Photosensitivity
  - Blurred, reduced, or fluctuating vision
  - Transient halo around lights
  - Scratchy, uncomfortable feeling
  - Spectacle blur

The Science Behind the Lenses

- Silicone-based materials
  - Positives
    - Exceptional \(O_2\) transmissibility
    - Durability
  - Negatives
    - Poor fluid transport
    - Lens binding
    - Surfaces extremely hydrophobic
    - Increased modulus
    - Lipid deposition

- Silicone hydrogel materials
  - Silicone rubber combined with conventional hydrogel monomers
    - Silicone component provides extremely high \(O_2\) permeability
    - Hydrogel component facilitates flexibility, wettability and fluid transport
  - Like combining oil & water
  - Over 20 years to be successfully created!

Dk of silicone? Approx. 400

The science behind silicone hydrogel lenses

Dk in Relation to Water Content

0 20 40 60 80 100
0 20 40 60 80 100

Silicone Hydrogel Lens Market Share

Silicone Hydrogel Lens Materials

Silicone Hydrogel Market Share Forecast

Oxygen: How Much Is Enough?

Oxygen: How Much Is Enough?

Overnight wear

– Holden & Mertz' (1984)
  – Assuming 4.0% edema, min. Dk/t = 87 for EW

  – Assuming 3.2% edema, min. Dk/t = 125 for EW

  – No stromal anoxia, min. Dk/t = 125 for EW

Daily wear

– Holden & Mertz’ (1984) =24


There Is Some Consensus

A minimum Dk/t is required:

- To achieve corneal swelling equivalent to no lens in EW
- To avoid corneal anoxia in overnight wear
- To avoid an increase in limbal hyperaemia in daily wear or extended wear
- To reduce bacterial binding for daily wear or extended wear

**Implications for limbal stem cells which are critical for the long term growth and repair**

- Patients exhibit widely different corneal swelling responses
- Corneal oxygen demand increases with age

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**Important Factors to Consider**

- These studies all represent the AVERAGE response
- 50% Pass 50% Fail

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**Dk, Dk/t and “Local Oxygen Transmissibility”**

Given two silicone hydrogel lenses, can one with a lower Dk have a higher Dk/t than the other?

<table>
<thead>
<tr>
<th>Lens</th>
<th>Dk</th>
<th>Dk/t</th>
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<tbody>
<tr>
<td>O₂OPTIX</td>
<td>110</td>
<td></td>
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<tr>
<td>ACUVUE OASYS</td>
<td>103</td>
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</table>

**Dk, Dk/t and “Local Oxygen Transmissibility”**

Given two silicone hydrogel lenses, can one with a lower Dk have a higher Dk/t than the other?

<table>
<thead>
<tr>
<th>Lens</th>
<th>Dk</th>
<th>Dk/t</th>
<th>Center Thickness (-3.00)</th>
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<tr>
<td>O₂OPTIX</td>
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<td>103</td>
<td>147</td>
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</table>
Oxygen Transmissibility Profile

**Oxygen Profiles (-3.00 sph.)**

![Image of Oxygen Profiles]

**Localized Oxygen Transmissibility at Lens Periphery**

![Image of Oxygen Profiles at Lens Periphery]

**Variables...**

1. There is a high variability in oxygen metabolism and no simple test to predict oxygen requirements for a given individual lens wearer.
2. Actual oxygen transmissibility (Dk/t) varies across a given lens profile and is significantly impacted by lens power.

**AND...**

**Variability in Lifestyle & Compliance**

![Image of Lifestyle & Compliance]

CIBA Vision, data on file 2004

72% desire some form of overnight wear!
They’re already doing it!

- 28% of 1-week lens wearers occasionally or routinely sleep in their lenses (Source: CIBA Vision, data on file, 2003)
- 84% of soft contact lens wearers have napped with lenses (Source: CIBA Vision, data on file, 2004)

Oxygen: How Much Is Enough?

  - Assuming 4.0% edema, \( \text{min. } \frac{Dk}{t} = 87 \) for EW
- Sweeney* (2003)
  - Assuming 3.2% edema, \( \text{min. } \frac{Dk}{t} = 125 \) for EW
  - No stromal anoxia, \( \text{min. } \frac{Dk}{t} = 125 \) for EW

Clinical Research = Populations
Clinical Care = Individuals

Surface Modifications

Shouldn’t we choose \( \frac{Dk}{t} \) with the least physiologically tolerant patient in mind?
Lens Surface Modifications

- Silicone elastomer materials generally display:
  - Decreased surface wettability
  - Increased lipid interaction
  - Accentuated lens binding
- Require “surface modification”

Surface Modifications

- O₂OPTIX: Permanent, chemically bonded plasma treatment for a smooth, continuous surface
- ACUVUE Night & Day: No permanent plasma treatment
- PureVision: Surface coating made up of silicate islands that do not completely cover the surface

Modulus

- Definition: Force per unit area required to produce a deformation
- Describes how well a material resists deformation
- Modulus is a material parameter
- Effective stiffness of a particular contact lens will also be influenced by its specific geometry
- A lens with a low modulus may still be relatively stiff if it has a thick and chunky design

<table>
<thead>
<tr>
<th>Name</th>
<th>Modulus (MPa)</th>
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<tbody>
<tr>
<td>NIGHT&amp;DAY</td>
<td>1.5</td>
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<tr>
<td>PureVision</td>
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<tr>
<td>O₂OPTIX</td>
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<td>ACUVUE OASYS</td>
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<tr>
<td>ACUVUE Advance</td>
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- ↑ modulus: Possible physiological effects
  - Mucin balls
  - Superior epithelial arcuate lesions (SEAL)
  - Contact Lens Induced Papillary Conjunctivitis (CLPC)

Modulus

- ↑ modulus
  - Improved handling
  - Less “draping” over cornea
    - Fitting implications
  - Possible masking of astigmatism
Mucin Balls

- Pearly, translucent, post-lens debris
  - mucin & lipid
  - common after EW of Si-H
  - 20-100 µm
  - tear film collapses, lipid contacts mucin, rolls up following lens / eye movement

- No effect on symptoms, vision or biomicroscopy
- Not related to age, gender or prescription
- Higher incidence found if:
  - steep cornea
  - 30 day EW vs. 6 day EW
  - no use of rewetting drops

Mucin Balls

- No complications over short term
- If severe:
  - reduce nights without removal
  - move the lens onto the sclera periodically
  - use rewetting drops am and pm
  - fit steeper lens, i.e., 8.4mm base curve

Superior Epithelial Arcuate Lesions (SEALs)

- Thin arcuate lesion superior cornea ~ 1mm from limbus
- Significant staining
- Occasionally underlying infiltrates
- Edges often irregular

SEAL (Epithelial Splitting)

- Mechanical forces from upper lid are transmitted to superior cornea resulting in epithelial chafing.
- May be related to
  - Improperly fit high modulus, stiff materials
  - Wearing schedule (EW)
  - Thick designs
  - Poorly blended curve junctions
  - Low water content?
  - Tight upper eye lids
  - Certain corneal topographies
SEAL (Epithelial Splitting)

Symptoms
- Pt’s often asymptomatic!
- Most common symptoms
  - FBS
  - Irritation

Contact Lens Papillary Conjunctivitis (CLPC)

Higher modulus?
- SiHy: ↑ incidence of “local” CLPC
  (≤ 2 zones involved)
- Low Dk/t: ↑ incidence of “general” CLPC
  (> 2 zones involved)
- N&D: Lower incidence 8.4 BC vs. 8.6 BC

High recurrence rate if refit same SiHy material and continue EW
Recurrence rate significantly reduced with DW of same SiHy material

Contact Lens Papillary Conjunctivitis (CLPC)

General CLPC
- Large, raised papillae of a cobblestone appearance
- Moderate to severe hyperaemia across the entire tarsus
- Moderate to severe patient symptoms, including itching or irritation, a stringy or ropy discharge, excessive movement of the lens and blurred vision due to this movement or coatings/discharge on lenses.

Local CLPC
- Involves papillae and hyperaemia confined to one or two areas of the upper tarsus only, usually in the central region nearest the lid margin
- Symptoms typically much milder than in general CLPC, with slight irritation or foreign body sensation often the only symptom.

Optics

NIGHT&DAY and O₂OPTIX
- Advanced aspheric lenses designed to optimize visual clarity

PureVision
- Aspheric optical design to correct spherical aberration

ACUVUE Advance and OASYS
- No asphericity
Optics

Two factors may influence lens power in fitting/refitting silicone hydrogel lenses:
1. Variations in optical designs require careful over-refraction in refitting.
2. Reversal of myopic creep.

Spherical Aberration
5 mm “Optic Zone”

Effect of Reduced Aberration

Examples:
- Plus Acuvue 2 lenses “act” more plus
  - Patient wearing +5.00 AV2
  - Switch to NIGHT & DAY, +5.50 needed?
- Minus Acuvue 2 lenses “act” more minus
  - Patient wearing -7.00 AV2
  - Switch to NIGHT & DAY, -7.50 needed?

“Myopic Creep”

Reversal of myopic creep

etafilcon A to lotrafilcon A - 3 month cross over: n=13
Lens Care & Silicone Hydrogel Lenses

Modern Lens Care Convenience
- Current one-step, no-rub, multipurpose (MPS) systems generally contain one of three antimicrobial agents:
  - Hydrogen peroxide
  - Polyhexamethylene biguanide (PHMB)
  - Polyquaternium-1 (Polyquad)

Introduction of Silicone Hydrogels
- Anecdotal reports of corneal staining
- Question of interaction between certain lenses and lens care products?

Summary

<table>
<thead>
<tr>
<th></th>
<th>Peroxide-based</th>
<th>Polyquad-based</th>
<th>PHMB-based</th>
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Summary
- Unacceptable staining is more likely when PureVision lenses are used with certain PHMB-based systems than when N&D lenses are used with the identical systems
- Staining is relatively rare with Polyquad-based regimens, and essentially non-existent with hydrogen peroxide-based systems
- Regimens with identical concentrations of PHMB can behave differently, depending on solution formulation

Summary
- Success of a given lens care regimen with conventional hydrogel lenses does not guarantee success of that same system with silicone hydrogel lenses (emphasis added)
- When refitting DW patients from conventional hydrogel lenses to silicone hydrogel lenses, we tend to blame discomfort on the new lens material (emphasis added)
- Must consider potential interaction between material and care regimen
“The ultimate key to success with these novel contact lens materials is to make specific lens care recommendations to every patient…”

- Dr. Jennifer Smythe


**Comfort & Adaptation**

**Comfort?**

- Silicone hydrogel lenses are stiffer than conventional HEMA-based materials
- Many patients will experience increased “awareness” when refit

**Educate & Set Proper Expectations**

- Discuss up front!
- Awareness may increase before it gets better (PMMA → RGP)

**So how do I decide?**

The “Pepsi Challenge”

Coca-Cola vs. Pepsi
The “Pepsi Challenge” vs. PEPSI

What’s going on?

Comfort and wettability

“Of the silicone hydrogel lenses used, balafilcon A (PureVision®) had the highest contact angles; galyfilcon A (Acuvue® Advance™) was the most wettable initially but rapidly developed contact angles similar to balafilcon A (Pure Vision); and lotrafilcon materials (NIGHT & DAY® and O2OPTIX™) retained the most wettable surface overall.”

End of day comfort and dryness

- Dumbleton² (2004)
  - Group of successful long term soft contact lens wearers were refitted with silicone hydrogel lenses (CIBA Vision Night & Day™)
  - DW basis and replaced monthly

End of day comfort and dryness

Dumbleton² (2004)

- Results:
  - Significantly better end-of-day comfort and less end of day dryness when compared with their habitual lenses
  - While end-of-day comfort remained the same throughout the study, there was actually less end of day dryness as the study progressed
  - The intensity of dryness symptoms at the end of the first month and throughout the second month was significantly lower than after the first day and first week wearing the silicone hydrogel lenses

Limbal Hyperemia

“...showed a significant decrease in limbal hyperemia within one month of refitting conventional hydrogel lens.”² (emphasis added)

“Bulbar and limbal hyperemia decreased significantly during the study. The reduction... occurred mainly between the baseline and 1 month visits.”² (emphasis added)

So how do I decide?

“Does this mean that the Pepsi Challenge was a fraud? Not at all. It just means that we have one reaction after taking a sip, and we have another reaction after drinking a whole can. In order to make sense of people’s cola judgments, we need to first decide which of those two reactions most interests us.” (emphasis added)

- Malcolm Gladwell
  As quoted in “blink”
“Most people have a desire to look for the exception instead of the desire to become exceptional.”

- John Maxwell

Questions & Discussion

Thank you!